NORACT - Data Dictionary Codebook

SCREENING

This section should be completed for <u>all</u> women seen in your clinic that are eligible for either type of cerclage, even if not a NORACT candidate

If you have any questions, please contact: lea.hansen@clin.au.dk

Data variable	Field Label	Options	Data source	Description
[record_id]	Record ID		Generated by REDCap	Unique REDCap ID for each participant.
[reg_country]	Please choose the participant's country of residence	1 Danmark (Denmark) 2 Norge (Norway) 3 Sverige (Sweden) 4 Suomi (Finland) 5 Ísland (Iceland) 6 United Kingdom		Insert the country of residence. This is the country where the woman is being recruited and will give birth. Not necessarily the same as her nationality.
[scr_name]	Insert the participant's full name Eg. Maria Madsen	Free text	Medical records	Insert name as it appears in her medical records.
[scr_dob]	Insert the participant's date of birth	Date(xx) – month (xx) – year(xxxx)	Medical records	Date of birth with a dash between day, month and year: e.g. 03-12-1992
[con_mail]	Participant's e-mail address for digital participant information leaflet and consent form.	text (email)	Medical records or directly from the participant in clinic	Make sure the e-mail is inserted correctly, as this will allow for information to be sent to the woman.
[scr_cpr_dk]	Insert the participants personal identification number	Digits	Medical records	Insert unique health record number.

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Data variable	Field Label	Options	Data source	Description
[scr_hist]	What is the obstetric history indicating eligibility? *Women with delivery up to 32 weeks might be considered depending on a clinical judgement	1 scr_hist __ 1: History of emergency/laboring cesarean section followed by a spontaneous singleton late miscarriage and/or PTB from 14+0 to 28+0* weeks 2 scr_hist __ 2: History with a prior elective vaginal cerclage placement but nonetheless a spontaneous late miscarriage and/or PTB between 14+0 and 28+0* weeks 3 scr_hist __ 3: History of a prior emergency cerclage with delivery between 14+0 and 28+0* weeks 4 scr_hist __ 4: Excisional cervical procedure (e.g. LLETZ, cold knife conisation) and a short pre-pregnancy cervix (e.g. short ectocervix with inspection or below 15-20 mm with ultrasound) 5 scr_hist __ 5: History of one or more deliveries GA 16+0 to 28+0 weeks and a clinical diagnosis of cervical insuffciency 6 scr_hist __ 6: History of three or more deliveries GA 16+0 to 36+6 weeks 99 scr_hist __ 99: Other	Medical records	Check all the options that apply to the participant's past obstetric history.
[scr_hist_other]	If you chose other, please elaborate	Free text	Medical records	This box opens if you chose other in

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Data variable	Field Label	Options	Data source	Description
				the previous question. Please elaborate.
[scr_elaborate]	Any comments on the participant's risks/history?	Free text	The clinician Medical records	Any other information you find relevant regarding her risk of preterm birth.
[scr_con]	Cervical procedures, how many?	1 | 1 2 | 2 3 | 3 4 | 4 5 | >4	Medical records, pathology reports	This box opens if you chose history of cervical procedures. Insert the total number of cervical surgical procedures.
[scr_con_other]	If you chose more than four, how many	Number more than four	Medical records	Insert the total number of cervical procedures if more than four.
[scr_con_type]	Cervical procedure, what type(s)?	1 | scr_con_type __ 1 | LLETZ/LLEEP (standard procedure in Denmark) 2 | scr_con_type __ 2 | Cold knife conisation 3 | scr_con_type __ 3 | Laser conisation 4 | scr_con_type __ 4 | Needle excision of the transformation zone (straight wire excision) 5 | scr_con_type __ 5 | Large loop excision of the transformation zone (loop electrosurgical excisional procedure)	Medical records	Choose the type of cervical procedures. You can choose more than one, if she had different types performed.
[scr_con_other_define]	Other, please define	Free text, type of cervical surgical procedure of none of the above	Medical records	This box opens if you chose other in the previous question. Please

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Data variable	**Field Label**	**Options**	**Data source**	**Description**
				elaborate.
[scr_con1_month]	Month of first cervical surgey procedure	Choose the correct month.	Medical records. Pathology reports.	For each procedure insert the month in which the procedure was performed. If not clearly written, then your best estimate from the notes.
[scr_con1_year]	Year of first procedure e.g. 2010	Year (xxxx)	Medical records. Pathology reports.	For each procedure insert the year in which the procedure was performed. If not clearly written, then your best estimate from the notes.
[con_height]	Height of LLETZ/conization in mm	Number in millimeters	Pathology reports.	If available insert the height of removed biopsy.
[scr_par]	Parity Every pregnancy beyond 22+0 weeks	Check the number that applies	Medical records. In ultrasound scan records (Astraia in Denmark).	Number of pregnancies that went beyond 22+0 weeks of gestation. Still births also counts. Early/late miscarriages before 22+0 weeks do not count.
[scr_par_other]	If you chose more than 8, how many? Insert parity beyond 22+0 weeks	Number, more than eight	Medical records. In ultrasound scan records (Astraia in Denmark).	Insert parity if >8
[scr_nulli]	Has this participant ever had a pregnancy beyond 14 weeks of gestation?	1 Yes 2 No	Medical records. In ultrasound scan records (Astraia in Denmark).	If you chose parity=0, please insert if she ever had a pregnancy beyond 14+0 weeks.
[scr_bmi]	Current BMI Insert in whole numbers	Whole number (xx)	Medical records. In the hospital referral note.	Insert most recent BMI at time of screening. Insert whole number, eg. 24.
[scr_smoking]	Smoking Current smoker at time of	1 Yes 2 No	Medical records.	Check if the participant has any cigarette use at time of screening.

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Data variable	Field Label	Options	Data source	Description
	screening			
[scr_ut_mal]	Does the participant have a congenital uterine malformation? e.g. Uterus didelphys, uterine septum, arcuate uterus	1 Yes 2 No	Medical records.	Check if the participant has a congenital uterine malformation. Check is also if has not required surgery.
[scr_ut_mal_type]	What type?	1 Uterus didelphys 2 Uterine septum 3 Arcuate uterus 99 Other	Medical records.	Insert type.
[scr_ut_mal_other]	Please elaborate	Free text.	Medical records.	This field opens only if you chose 'other' in the above field. Describe the malformation in more detail.
[scr_uss]	Was a transvaginal ultrasound scan performed during this clinical visit?	1 Yes 2 No	Medical records. Ultrasound scan reports.	Even if you don't have the measurements, please check if a scan was performed.
[scr_cx_us]	Cervical length from internal os to external os in millimeters at screening visit (ultrasound). Insert uss measurement in millimeters	Number in millimeters.	Medical records. Ultrasound scan reports.	Insert the measurements. If more than one, insert the shortest measurements.
[scr_cx_us_2]	Cervical length from external os to the bladder	Number in millimeters	Medical records. Ultrasound scan reports.	Insert the measurements from the bladder fold to the external os. This measurement can be easier to achieve than the internal os to the external in non-pregnant women.

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Data variable	Field Label	Options	Data source	Description
[scr_uss_info] Show the field ONLY if: [scr_uss]=1	Please consider e-mailing your ultrasound measurement to: auh.noract@rm.dk for quality control. Ensure no patient identification details are present.	Information		
[scr_spec]	Was a speculum and digital vaginal exam performed?	1 Yes 2 No	Medical records.	Check if a pelvic exam was performed at the screening visit.
[scr_cx_oe]	Cervical length (millimeters) based on digital and visual inspection. Insert you best estimate. Insert length of cervix in millimeters	Number in millimeters.	Medical records.	Combining the digital exam of the cervix with the visual inspection from the speculum exam, insert your best estimate of the cervical length. Insert both your shortest and longest estimate.
[scr_preg]	Is the patient currently pregnant? State if the participant is pregnant on date of screening	1 Yes 2 No 99 Unknown	Medical records.	Check if the patient is pregnant at time of screening, even if it has not yet been confirmed by USS.
[scr_weeks]	Week of gestational age e.g. 5	Gestational week	Medical records.	If yes to the above questions, you are asked to insert gestational age. Insert the current week of her gestational age. If no USS yet, provide the best estimate.
[scr_days]	Days of gestational age e.g. 3		Medical records.	If yes to the above questions, you are asked to insert gestational age. Insert the current day (0-6) of her gestational age. If no USS yet, provide the best estimate.

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Data variable	**Field Label**	**Options**	**Data source**	**Description**
[scr_surgeon]	Does this participant need to be discussed with laparoscopic surgeon to decide eligibility for the trial?	1 Yes 2 No	Medical records. The clinician.	If something in the past medical history raises concerns regarding safety of a laparoscopic procedure, check this field and arrange a discussion with your local team.
[scr_eligible]	In your opinion as responsible clinician, is this patient eligible to participate in the NORACT trial?	1 Yes 2 No 3 Maybe	Medical records. The clinician.	Important to distinguish between eligibility and consent to participate. If the woman is eligible but declines, you should check box 1: Yes.
[scr_not_elig_descr]	Please describe why she is not eligible?	Free text	Medical records. The clinician.	Provide details on why she is not eligible.
[screening_laparoscopic_si te_complete]	Section Header: Form Status Complete?	dropdown		Please set as complete when you have completed all fields.

SIGN: STATEMENT FROM PERSON PROVIDING VERBAL INFORMATION

If you have any questions, please contact: lea.hansen@clin.au.dk

Data variable	Field Label	Options	Data source	Description
[statement_note_uk]	In this section we will ask you to confirm by signature that you have provided the participant with verbal information about the NORACT trial.	descriptive		
[statement_name_uk]	Insert your full name Eks. Maria Madsen	text		Insert the name of the physician who provided the participant with the verbal and written information material.
[statement_sign_uk]	I hereby declare that the trial participant has received verbal and written information about NORACT along with the oppourtunity to ask questions about the trial. In my opinion, the participant has received sufficient information to decide about participation in the trial. Click the green 'Add signature', to sign the form.	Insert your signature using the computer mouse		By signing this field you declare that you have provided the participant with verbal and written information.
[con_info_uk]	The next step is to send the participant information leaflet inkluding the digital consent form to the participant via e-mail.Important: You shall also send the consent form if the participant declines to participate. The woman needs to decide if we	descriptive		In some countries you use paper consent forms. You can still send the information leaflet via e-mail using this field. Another field for you to upload the signed consent form will be available.

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Data variable	Field Label	Options	Data source	Description
	can collect data on her, to gain information on decliners. Arrange a telephone follow-up with the participant within a few days.			
[send_consent_uk1]	Press 'Send' to send 'Participant information leaflet and consent form' to the participant (Send)	Press the yellow ‘send’ button.		Make sure your e-mail is open. Once you press the send button, a new window will appear and an automated e-mail is ready to be sent, containing link to the participant information leaflet and consent form.
[sign_statement_from_person_providing_verbal_inform_ complete]	Section Header: Form Status Complete?	0 Incomplete 1 Unverified 2 Complete		Please check as complete once you have signed and provided the information to the participant.

RANDOMISATION If you have any questions, please contact: lea.hansen@clin.au.dk				
Data variable	**Field Label**	**Options**	**Data source**	**Description**
[ran_consent]	Is written consent obtained? Please check by opening the instrument 'condk', 'conno', 'conse', 'conis', confi' or 'conuk (found on the left side of your screen).	1 Yes 2 No	REDCap or paper format	Ensure that consent is obtained and stored in REDCap prior to randomisation.
[ran_date]	Insert date of randomisation Eg. 23-03-2023 or use the calendar icon	Day – month - year / XX-XX-XXXX		Insert the date you are completing this section. You can easily use the calendar icon.
[ran_treat]	Randomisation	1 Vaginal cerclage (control) 2 Laparoscopic cerclage (intervention)		Press the green button that says 'RANDOMIZE' and the system will tell you which procedure the participant is allocated to.
[randomisation_laparoscopi c_site_complete]	Section Header: Form Status Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete		Please mark as complete.

ALLOCATION AND BOOKING If you have any questions, please contact: lea.hansen@clin.au.dk				
Data variable	Field Label	Options	Data source	Description
The next box will only appear if the participant is randomized to a transvaginal procedure				
[letter_tvc_uk]	Press 'Send' to send 'Information on treatment' to the participant (Send)	text (date_dmy), Required		Make sure your e-mail is open. Once you press the send button, a new window will appear and an automated e-mail is ready to be sent, containing link to the allocation letter, which informs the participant of her allocated procedure and the next steps.
The next two boxes will only appear if the participant is randomized to a laparoscopic procedure				
[book_lac]	Please arrange booking for a laparoscopic cerclage procedure.	Descriptive, Required		Arrange a laparoscopic cerclage procedure for the participant in your department.
[letter_lac_uk]	Press 'Send' to send 'Information on treatment' to the participant (Send) Click on 'today' to register the date of sending the letter	text (date_dmy), Required		Make sure your e-mail is open. Once you press the send button, a new window will appear and an automated e-mail is ready to be sent, containing link to the allocation letter, which informs the participant of her allocated procedure and the next steps.
To be completed for regardless of allocation				

ALLOCATION AND BOOKING If you have any questions, please contact: lea.hansen@clin.au.dk				
Data variable	**Field Label**	**Options**	**Data source**	**Description**
[letter_allocation_date]	Today's date (when you send the letter)	text (date_dmy), Required		Insert the date on which you completed this section and sent the letter to the participant.
[allocation_and_booking_co mplete]	Section Header: Form Status Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete		Please mark as complete.

HISTORY

*In this section you collect data on all previous pregnancies. You should **not** collect data in this section on the pregnancy that occurred during the trial.*

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Data variable	Field Label	Options	Data source	Description
[past_obst_descr]	You are now collecting data on [scr_name] ([scr_age]) In this section you will collect data on each of the participant's previous pregnancies.	descriptive		
[past_obst_no]	State the total number of pregnancies beyond 14 weeks of gestation		Medical records. Ultrasound scan reports.	Check the number of pregnancies that exceeded 14+0 weeks of gestation. Include all pregnancies over 14+0 weeks, including those that were terminated after 14+0 weeks. You can choose up to 10.
[past_obst_1]	PREGNANCY NUMBER 1	descriptive		According to the number of pregnancies the patient has had, you should collect data on each pregnancy individually. You can collect data in any order of pregnancies you prefer.
[past_obst_end_1]	State the date the pregnancy ended Eg. 23-03-2023 or use the calendar icon	text (date_dmy), Required	Medical records. Ultrasound scan reports.	Insert the date of end of the first pregnancy over 14+0 weeks. Could be date of birth, loss or termination.
[past_obst_ga_week_1]	Gestational week when pregnancy ended e.g. 22	text (number, Min: 14, Max: 42), Required	Medical records. Ultrasound scan reports.	Insert the gestational age when the first pregnancy ended.
[past_obst_ga_days_1]	Day of gestational age when pregnancy ended e.g. 4	dropdown, Required	Medical records. Ultrasound scan reports.	Insert the gestational age when the first pregnancy ended.

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Data variable	Field Label	Options	Data source	Description
[past_obst_mis_1]	Did this pregnancy end in a miscarriage? (including induced, spontaneous or missed miscarriage)	1 Yes 2 No	Medical records. Ultrasound scan reports.	Check whether the pregnancy ended with a loss.
[past_obst_mis_def_1]	Describe the miscarriage	1 Induced due to intrauterine death (missed miscarriage) 2 Induced due to poor prognosis (e.g. exposed membrane PPROM) 3 Induced due to fetal anomaly 4 Spontaneous miscarriage 5 Other	Medical records. Ultrasound scan reports.	This box only appears if you chose yes to miscarriage above.
[past_obst_mis_com_1]	Comments regarding the miscarriage	Free text	Medical records. Ultrasound scan reports.	If you want to add anything that may be of importance, you can insert free text here.
[past_obst_del_ind_1]	Onset of labour?	1 Spontaneous labour contrations 2 PPROM 3 PROM 4 Induction of labour 5 C-section	Medical records. Ultrasound scan reports.	This box only appears if you chose No to miscarriage above. Choose the **onset** of labour.

HISTORY

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Data variable	Field Label	Options	Data source	Description
[past_obst_del_mode_1] Show the field ONLY if: [past_obst_mis_1]=2	Mode of birth?	1 Unassisted vaginal delivery 2 Assisted vaginal (ventouse or forceps) 3 Planned caesarean section 4 Emergency caesarean section before labor 5 Emergency CS during 1st stage of labour 6 Emergency CS during 2nd stage of labor (fully dilated) 7 Emergency CS unknown stage of labour	Medical records. Ultrasound scan reports.	Insert the **mode** of birth
[past_obst_sing_1]	Was it a singleton pregnancy?	1 Yes 2 No	Medical records. Ultrasound scan reports.	If more than one fetus, check no.
[past_obst_tvc_1]	Did the patient have a transvaginal cerclage in this pregnancy?	1 Yes 2 No	Medical records.	If any type of **transvaginal** cerclage was used in this pregnancy, choose yes.
[past_obstr_tvc_type_1]	Type of cerclage	1 Planned transvaginal cerclage 2 Exam-indicated cerclage 3 Ultrasound indicated cerclage	Medical records.	**Planned transvaginal:** Was planned before pregnancy or during first trimester. Inserted when asymptomatic. **Exam-indicated:** Exposed membranes. **Ultrasound indicated:** Short cervix on ultrasound but not exposed membranes.

HISTORY

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Data variable	Field Label	Options	Data source	Description
[past_obst_tac_1]	Did the patient have an abdominal cerclage in this pregnancy?	1 Yes 2 No	Medical records. .	If a transabdominal cerclage was in situ during this pregnancy.
[past_obst_tac_rem_1]	When was the abdominal cerclage removed? (best estimate) Eg. 23-03-2023 or use the calendar icon	text (date_dmy, Min: 2000-01-01, Max: 2023-01-01), Required	Medical records.	Insert date of removal of transabdominal cerclage. (to be a NORACT participant it is requirement that she did not have a transabdominal cerclage when randomized)
[past_obst_tac_rem_why_1] Show the field ONLY if: [past_obst_tac_1]=1	Why was the abdominal cerclage removed?	notes, Required	Medical records.	
[history_complete]	Section Header: Form Status Complete?	0 Incomplete 1 Unverified 2 Complete		Check as complete.

SURGERY If you have any questions, please contact: lea.hansen@clin.au.dk				
Data variable	**Field Label**	**Options**	**Data source**	**Description**
[proc_info]	You are now collecting data on the surgical procedure for [scr_name] ([scr_dob]) This participant was randomised to [ran_treat]	descriptive		
[proc_type]	Which cerclage did the participant receive int the NORACT trial	1 Laparoscopic cerclage 2 Vaginal Cerclage 3 No cerclage was inserted before 16+0 weeks	Medical records.	Insert the actual procedure the participant received. Also if this was not the surgery she was randomized to.
[proc_non_adherence]	It appears that this participant did not receive her allocated treatment procedure. Please state why.	1 Surgical related failure to apply the allocated procedure 2 Patient choice 99 Other	Medical records.	If you chose a different procedure than what she was randomized to, this will appear. Please insert why she didn't receive her allocated procedure.
[proc_nonadherence_oth]	Other, please describe	Free text		You can add free text regarding the non-adherence in this box.
[proc_late] Show the field ONLY if: [proc_type]=3	Was a cerclage inserted after 16+0 weeks in this pregnancy?	1 Yes 2 No	Medical records.	This box appears if you chose that no cerclage was inserted before 16+0 weeks.
[proc_non_adherence_why]	Comments	Free text	Medical records.	Comments regarding the late or missing cerclage procedure.

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Data variable	**Field Label**	**Options**	**Data source**	**Description**
[proc_date]	Insert the date of the procedure Eg. 23-03-2023 or use the calendar icon	Date	Medical records.	Insert the date of the surgery.
[proc_surgeon]	Insert initials of the surgeon performing the procedure	Free text	Medical records.	Insert initials (first letter of first name and first letter of last name) of the primary surgeon
[proc_site_lac_dk]	Insert name of site where the procedure was performed	Dropdown	Medical records.	From the drop down menu you can choose the site where the procedure was performed.
[proc_type_robot] Show the field ONLY if: [proc_type]=1	Was the procedure performed by robot-assisted laparoscopy?	1 Yes 2 No	Medical records.	Choose 'yes' if the surgery was performed via robot-assisted laparoscopy. Choose 'No' if the procedure was performed by 'regular' laparoscopy.
[lac_ports] Show the field ONLY if: [proc_type]=1	Number of ports	1 2 2 3 3 4 4 5 5 6 66 Unknown	Medical records.	Insert number of ports. All ports count, including the camera port.
[proc_exp]	Surgeon's experience - state the years since qualification as a consultant/specialist in obstetrics/gyneocology	Number	From yourself or from your colleague.	Insert the number of years (whole years) since the operating surgeon qualified as a specialist/consultant in obstetrics and gynecology.

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Data variable	**Field Label**	**Options**	**Data source**	**Description**
[proc_preg]	Timing of procedure	1. Pre-pregnancy 2. During pregnancy	Medical records.	Choose if the patient was pregnant at time of procedure. If she was pregnant but unaware choose 'during pregnancy'
[proc_ga_week]	Week of gestational age at time of cerclage procedure e.g. 13	Insert number of gestational week	Medical records.	If she was pregnant, insert the week of her gestational age at time of procedure. Choose the most correct gestational age available.
proc_ga_days]	Day of gestational age at time of cerclage procedure e.g. 5	Insert day of gestational age	Medical records.	If she was pregnant, insert the day of her gestational age at time of procedure. Choose the most correct gestational age available.
[proc_anae]	Anaesthesia	1 General 2 Regional	Medical records.	Choose type of anesthesia. If converted choose the final type.
[proc_dur]	Duration of surgery in minutes	text (number, Min: 10, Max: 300), Required	Medical records.	Insert surgery time in minutes.
[lac_manipulator] Show the field ONLY if: [proc_type]=1	Intra uterine device during procedure? eg. hegar, manipulator, currete	1 Yes 2 No	Medical records.	For lap. Cerclage only. Check whether a device was used during the procedure.
[proc_mat]	Cerclage material	1 Multifilament (eg. mersilene, Ti-Cron) 2 Monofilament (eg. ethilon) 99 Other 66 Unknown	Medical records.	Insert type of suture. If other you can elaborate in the next field.

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Data variable	Field Label	Options	Data source	Description
[lac_knot]	Placement of knot(s)	1 Anterior 2 Posterior 66 Unknown	Medical records.	If the knot is tied in front between the bladder and the uterus choose 'anterior'. If the knot was tied at the back of the uterus choose ' posterior'.
[proc_uss]	Was a transvaginal ultrasound examination performed after the procedure?	1 Yes 2 No	Medical records.	Check whether an ultrasound scan was performed on the same day as the procedure
[proc_cx]	Cervical length from stitch to the external os in millimeters Lenght in millimeters, USS on the same day as the procedure	Number in millimeters	Medical records.	Insert the measurements. If more than one, insert the shortest measurements.
[proc_cx_2]	Overall cervical lenght from internal os to the external os Lenght in millimeters, USS on the same day as the procedure	Number in millimeters	Medical records.	Insert the measurements. If more than one, insert the shortest measurements.
[proc_uss_fun]	Was cervical funneling present?	1 Yes 2 No	Medical records.	Check if there is dilatation of the internal part of the cervical canal.
[proc_daycase]	Did the participant stay in hospital for more than 24 hours?	1 Yes 2 No	Medical records.	If the participant was operated in day surgery and left the hospital within 24 hours select no.
[proc_days]	How many days did the participant stay in hospital?	Insert number of days	Medical records.	If you choose yes above, please state how many days she stayed in hospital round up to nearest whole number.

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Data variable	Field Label	Options	Data source	Description
[proc_bloodloss]	Blood loss during procedure Insert loss in milliliters	text (number, Min: 0, Max: 2000), Required	Medical records.	Insert the best estimate of blood loss during the surgery.
proc_conv]	Conversion to laparotomy?	1 Yes 2 No	Medical records.	If for any reason the surgery was converted to open surgery check YES.
[lac_ab]	Administration of antibiotics during procedure?	1 Yes 2 No	Medical records.	Check if antibiotics was administered within 24 hours of the surgery. Both planned or non-planned administration.
[lac_add_proc]	Additional procedures performed during surgery (e.g. hysteroscopy, removal of endometriosis)	1 Yes 2 No	Medical records.	If any additional procedures were performed. Both planned and non-planned.
[lac_add_proc_type]	Which aditional procedure(s)	1 lac_add_proc_type ___1 Hysterocopy 2 lac_add_proc_type ___2 Removal of endometriosis 3 lac_add_proc_type ___3 Removal of ovarian cyst 4 lac_add_proc_type ___4 Release of abdominal adhesions 99 lac_add_proc_type ___99 Other	Medical records.	If yes to above, choose which type of additional procedure. You can choose more than one.
[tvc_method]	Method used	1 Purse string with bladder mobilisation 2 Purse string without bladder mobilisation	Medical records.	Only for transvaginal cerclage. 1= Shirodkar, 2 = McDonald's
[tvc_no_sut]	Number of sutures	1 1 2 2	Medical records.	Sometimes an additional suture is used above the first or to strengthen the first.

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Data variable	**Field Label**	**Options**	**Data source**	**Description**
[proc_pprom]	PPROM during procedure?	1 Yes 2 No	Medical records.	Only of the patient was pregnant during the procedure. Did her waters break?
[surgery_complete]	Section Header: Form Status Complete?	0 Incomplete 1 Unverified 2 Complete	Medical records.	Mark as complete

30 DAYS SURGERY

This section must be completed 30 days after the surgical procedure. A reminder will be sent by the study team to let you know when it is time to complete the form.

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Data variable	Field Label	Options	Data source	Description
[surg_compl_info]	You are about to collect data on surgical complications for [scr_name] ([scr_dob]). Please note that the time frame covers 30 days from the procedure ([proc_date]).	descriptive		This box will tell you name and DOB of the participant to allow you to verify that you are collecting data on the correct participant.
[surg_compl_inf]	Postoperative infection leading to antibiotic treatment within 30 days of the procedure ([proc_date])? Time frame 30 days of procedure	1 Yes 2 No	Medical records.	From the sources available (hospital notes, GP correspondence letters etc) check if the participant received antibiotics within 30 days of the surgery. All antibiotic treatment counts.
[surg_compl_inf_icu]	Post operative infection leading to ICU admission within 30 days of the procedure ([proc_date])?	1 Yes 2 No	Medical records.	Only for ICU admission DUE to infection.
[surg_compl_organs]	Perforation of the internal organs within 30 days of the procedure ([proc_date])? Time frame 30 days of procedure	1 Yes 2 No	Medical records.	Confirmed perforation of the internal organs. Even small lacerations that was treated during the procedure must be noted.

30 DAYS SURGERY

This section must be completed 30 days after the surgical procedure. A reminder will be sent by the study team to let you know when it is time to complete the form.

If you have any questions, please contact: lea.hansen@clin.au.dk

Data variable	Field Label	Options	Data source	Description
[surg_compl_organs_spec] Show the field ONLY if: [surg_compl_organs]=1	Which organs	1 Uterus 2 Bladder 3 Intestine 4 Ureteres 99 Other	Medical records.	
[surg_compl_organs_descr] Show the field ONLY if: [surg_compl_organs]=1	Please describe what kind of damage and the treatment/consequences for the participant.	Free text	Medical records.	Describe how the injury/laceration was treated.
[surg_compl_reop]	Was the patient re-operated within 30 days of the procedure ([proc_date])? Time frame 30 days from procedure	radio, Required 1 Yes 2 No	Medical records.	Abdominal re-operations due to complications from the primary procedure.

30 DAYS SURGERY

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Data variable	Field Label	Options	Data source	Description
[surg_compl_icu]	Was the participant admitted to ICU within 30 days of the procedure ([proc_date])? Time frame 30 days from procedure	1 Yes 2 No	Medical records.	ICU admission due to any cause but within 30 days of the surgery. Does NOT have to be related to the surgery.
[surg_compl_icu_reason] Show the field ONLY if: [surg_compl_icu]=1	Please note the main reason for ICU admission	notes, Required	Medical records.	Elaborate on the cause for ICU admission.
[surg_compl_thrombosis]	Did the participant have a thromboembolic event ? Time frame 30 days from procedure	radio, Required 1 Yes 2 No	Medical records.	Confirmed thromboembolic event (defined as deep vein thrombosis, pulmonary embolism or stroke) within 30 days of the procedure?

30 DAYS SURGERY

This section must be completed 30 days after the surgical procedure. A reminder will be sent by the study team to let you know when it is time to complete the form.

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Data variable	Field Label	Options	Data source	Description
[surg_compl_arrest]	Did the participant have cardiopulmonary arrest within 30 days of the procedure? Time frame 30 days from procedure	1 Yes 2 No	Medical records.	Check even if not related to the surgery.
[surg_compl_death]	Did the particpant die within 30 days of the procedure? Time frame 30 days from procedure	radio, Required 1 Yes 2 No	Medical records.	Check even if not related to the surgery.
[surg_compl_mat_death] Show the field ONLY if: [surg_compl_death]=1	Please state cause of death	notes, Required	Medical records.	If she passed away, insert the cause of death as written in the medical notes.

30 DAYS SURGERY

This section must be completed 30 days after the surgical procedure. A reminder will be sent by the study team to let you know when it is time to complete the form.

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Data variable	Field Label	Options	Data source	Description
[surg_compl_other]	Other complications within 30 days of the procedure? Time frame 30 days from procedure	Free text	Medical records.	Free text field to note any other complications or notes related to the surgery.
[dayssurgery_complete]	Section Header: Form Status Complete?	dropdown 0 Incomplete 1 Unverified 2 Complete		Mark as complete.

NORACT PREGNANCY

In this section you collect data on the first pregnancy beyond 14 weeks and 0 days following randomisation.

If you have any questions, please contact: lea.hansen@clin.au.dk

Data variable	Field Label	Options	Data source	Description
[noract_info]	You will now collect data on the 'NORACT pregnancy' for [scr_name] ([scr_dob]). Defined as first viable pregnancy (USS detected heartbeat) beyond fourteen weeks following randomisation.	descriptive		
[noract_due]	Insert ultrasound determined due date Eg. 23-03-2023 or use the calendar icon	Date or use the calendar icon	Medical records. Ultrasound scan reports.	if USS not performed insert best determined due date
[noract_art]	Did the patient get assisted reproduction therapy (fertility treatment) for this pregnancy)?	1 Yes 2 No	Medical records.	State if fertility treatment was used for this pregnancy. Any types of fertility treatment counts.
[noract_singl]	Is this a singelton gestation?	1 Yes 2 No	Medical records.	If this is a twin pregnancy check 'NO' as this is not a singleton pregnancy.
[noract_resc_tvc]	Was an exam-indicated/rescue transvaginal cerclage inserted during this pregnancy?	1 Yes 2 No	Medical records.	If at any point during the pregnancy an additional cerclage was inserted.
[noract_resc_tvc_ga_week] [noract_resc_tvc]=1	Gestational week of insertion of exam-indicated/rescue cerclage	text (number, Min: 16, Max: 30), Required	Medical records.	If yes to above insert the gestational week of the procedure of the additional cerclage.

NORACT PREGNANCY

In this section you collect data on the first pregnancy beyond 14 weeks and 0 days following randomisation.

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Data variable	Field Label	Options	Data source	Description
[noract_resc_tvc_ga_days] Show the field ONLY if: [noract_resc_tvc]=1	Day of gestational age for insertion of rescue cerclage e.g. 3	1 0 2 1 3 2 4 3 5 4 6 5 7 6	Medical records.	If yes to above insert the gestational day of the procedure of the additional cerclage.
[noract_prog]	Did the participant receive treatment with vaginal progesterone?	1 Yes 2 No	Medical records.	Check this box if progesterone was prescribed.
[noract_prog_week] Show the field ONLY if: [noract_prog]=1	From which gestational week? e.g. 16	number	Medical records.	Insert the gestational week from which progesterone treatment was prescribed.
[noract_prog_dose] Show the field ONLY if: [noract_prog]=1	Which dose of progesterone was prescribed?	1 100 mg 2 200 mg 99 Other	Medical records.	Insert the prescribed dose of progesterone.
[noract_betha]	Was the participant administered lung maturation (betamethasone) < 34 weeks of gestation	1 Yes 2 No	Medical records.	Also if she didn't complete the full dose, check this box.

NORACT PREGNANCY

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Data variable	Field Label	Options	Data source	Description
[noract_toco]	Was the participant administered tocolytics < 34 weeks of gestation?	1 Yes 2 No	Medical records.	If for any reason and duration check if she was treated with tocolytics.
[noract_common_inf]	Was the participant treated with antibiotics for a common infection from time of randomisation to 42 days after delivery? E.g. bladder infection, airway infection etc. Not leading to ICU admission.	1 Yes 2 No	Medical records.	Any type of antiobiotic treatment from time of randomisation to 42 days after birth.
[noract_common_inf_type] Show the field ONLY if: [noract_common_inf]=1	On which indication?	1 noract_common_inf_type ____ 1 PPROM 2 noract_common_inf_type ____ 2 Exposed membranes 3 noract_common_inf_type ____ 3 Urinary tract infection 4 noract_common_inf_type ____ 4 Airway infection 7 noract_common_inf_type ____ 7 Unknown source 99 noract_common_inf_type ____ 99 Other infection	Medical records.	Check all that apply.
[noract_ser_inf]	Was the participant treated for a serious infection that led to ICU admission from time of randomisation to 42 days after delivery?	1 Yes 2 No	Medical records.	Any type of infection leading to ICU admission from time of randomisation to 42 days after birth.

NORACT PREGNANCY

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Data variable	Field Label	Options	Data source	Description
[noract_ser_inf_icu] Show the field ONLY if: [noract_ser_inf]=1	Please elaborate on the infection that led to ICU admission	notes, Required		
[noract_ga_week]	Insert gestational week when pregnancy ended. Please note this is the primary outcome for NORACT. Please ensure you enter correct details. e.g. 33	Number from 14-42 weeks	Medical records.	Insert the week of her gestational age when the pregnancy ended.
[noract_ga_days]	Day of gestational age when pregnancy ended. Please note this is the primary outcome for NORACT. Please ensure you enter correct details. e.g. 5	1 0 2 1 3 2 4 3 5 4 6 5 7 6 Choose a day 0-6	Medical records.	Insert the day of gestational age when her pregnancy ended.
[noract_pprom]	Did the participant have PPROM (preterm premature rupture of membranes)?	1 Yes 2. No	Medical records.	Confirmed rupture of membranes before 37 weeks of gestation.
[noract_pprom_week] Show the field ONLY if: [noract_pprom]=1	Week of gestational age for PPROM? e.g. 32	text (number, Min: 14, Max: 42), Required	Medical records.	If yes to PPROM insert the week of her gestational age when PPROM was confirmed.

NORACT PREGNANCY

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Data variable	Field Label	Options	Data source	Description
[noract_pprom_days] Show the field ONLY if: [noract_pprom]=1	Day of gestational age for PPROM? e.g. 3	1 0 2 1 3 2 4 3 5 4 6 5 7 6	Medical records.	If yes to PPROM insert the day of her gestational age when PPROM was confirmed.
[noract_onset]	Tick the box that best describe onset of her labour	1 Spontaneous labour onset 2 Induction of labour 3 Caesarean section	Medical records.	This describes the ONSET of er labour, so even if she ended up having a c-section, if the onset was PPROM, PROM, contractions choose number 1.
[noract_mode_birth]	Insert the mode of birth For twins you can choose more than one option if applicable	1 noract_mode_birth ____ 1 Unassisted vaginal delivery 2 noract_mode_birth ____ 2 Assisted vaginal delivery (forceps or ventouse) 3 noract_mode_birth ____ 3 Planned caesarean section 4 noract_mode_birth ____ 4 Non-planned caesarean section	Medical records.	This is the MODE of birth. Regardsless of how the onset was, what was the mode of birth. You can choose two for twins.

NORACT PREGNANCY

In this section you collect data on the first pregnancy beyond 14 weeks and 0 days following randomisation.

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Data variable	Field Label	Options	Data source	Description
[noract_tvc_remove] Show the field ONLY if: ([proc_type]=2) OR ([noract_res c_tvc]=1)	Insert date of removal of the transvaginal cerclage.	text (date_dmy, Min: 2023-12-01, Max: 2030-12-01), Required	Medical records.	For TVc's only. Insert the date when the cerclage was removed. Insert the actual date and not the planned date (unless they are the same).
[noract_uss_20]	Was the cervical lenght measured with transvaginal ultrasound in gestation age 18+0-21+6?	1 Yes 2 No	Medical records. Ultra sound scan reports.	
[noract_uss_20_mm_2] Show the field ONLY if: [noract_uss_20]=1	Overall cervical length from the internal os to the external os in millimeters. Insert the shortest measured value.	Insert number in millimeters.	Medical records. Ultra sound scan reports.	
[noract_uss_20_mm_3] Show the field ONLY if: [noract_uss_20]=1	Was funneling present during this scan?	1 Yes 2 No	Medical records. Ultra sound scan reports.	
[noractpregnancy_complete]	Section Header: Form Status Complete?	0 Incomplete 1 Unverified 2 Complete		Mark as complete.

NEONATAL

In this section you collect data on the neonatal outcome from the first pregnancy beyond 14 weeks and 0 days following randomisation.

If you have any questions, please contact: lea.hansen@clin.au.dk

Data variable	Field Label	Options	Data source	Description
[noract_neo_info]	You will now collect neonatal data from the pregnancy beyond 14 weeks of gestation following randomisation for [scr_name] ([scr_age]).	descriptive		
[twins_head] Show the field ONLY if: [noract_singl]=2	BABY NUMBER 1 (FOR TWINS)	descriptive		If you previously marked that this is a twin pregnancy, the database will allow you to collect data for each baby separately.
[noract_neo_dob]	Date of birth Eg. 23-03-2023 or use the calendar icon	text (date_dmy, Min: 2023-12-01, Max: 2029-12-01), Required	Medical records.	Insert the baby's date of birth (or date of miscarriage)
[noract_neo_death]	Did the baby die between 14+0 weeks of gestation to four weeks after expected due date?	1 Yes 2 No	Medical records.	Any baby death from GA 14+0- four weeks after due date. Covers stillbirth, miscarriage (spontaneous or induced) and neonatal death.
[noract_neo_liveborn]	Was the baby live-born?	1 Yes 2 No	Medical records.	Only if yes to above. State whether the baby showed signs of life.

NEONATAL

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Data variable	Field Label	Options	Data source	Description
[noract_neo_death_ga_week]	Week of gestational age at time of death e.g. 23	Number of weeks	Medical records.	Only if yes to baby death. State the gestational week when death was **confirmed.** This may differ from time of birth if intra uterine death was confirmed in GA 25+2 and birth was in 25+4.
[noract_neo_death_ga_days]	Day of gestational age at time of death e.g. 2	1 0 2 1 3 2 4 3 5 4 6 5 7 6	Medical records.	Only if yes to baby death. State the gestational week when death was **confirmed.** This may differ from time of birth if intra uterine death was confirmed in GA 25+2 and birth was in 25+4.
[noract_neo_death_age]	Insert postnatal age (in days) at time of death Days	Number of days	Medical records.	If the baby was liveborn but dies, insert number of full days at time of death.
[noract_neo_death_date]	Date of the neonatal death or the date on which intrauterine death was confirmed Eg. 23-03-2023 or use the calendar icon	Date or calendar icon	Medical records.	Only if yes to baby death. State the calendar date when death was **confirmed.**
[noract_neo_death_cause]	Cause of death?	text, Required	Medical records.	Only if yes to baby death. State the cause of death as written in the medical notes.

NEONATAL

In this section you collect data on the neonatal outcome from the first pregnancy beyond 14 weeks and 0 days following randomisation.

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Data variable	Field Label	Options	Data source	Description
[noract_neo_bw]	Enter the birthweight in grams e.g. 980	Number - grams	Medical records.	Enter the first registered birthweight in grams.
[noract_neo_adm]	Was the baby admitted to hospital after birth but before 28 days of life?	1 Yes 2. No	Medical records.	Mark yes if either discharged and admitted before 28 days of life or directly admitted from the delivery unit to a neonatal unit. Admission to any ward counts. (NICU (neonatal ICU, SCBU (special care baby unit) and maternity ward.)
[noract_neo_adm_dur]	Insert number of consecutive days in hospital post delivery incuding NICU, SCBU and maternity ward.	text (number, Min: 0, Max: 160), Required	Medical records.	If yes to above, insert number of whole days (if wards changed during admission, write duration of the overall stay regardless of wards)
[noract_neo_cns]	Did the baby suffer from CNS morbidity? (check all that apply) Time frame: From birth to 4 weeks after expected due date	1 noract_neo_cns___ 1 Intraventricular Hemorrhage Grade III and IV 2 noract_neo_cns___ 2 Periventricular leukomalacia 3 noract_neo_cns___ 3 None	Medical records.	Check only if confirmed.
[noract_neo_gastro]	Did the baby suffer from gastrointestinal morbidity (check all that apply) Time frame: From birth to 4 weeks after expected due date ([noract_due])	1 noract_neo_gastro ___ 1 Necrotizing enterocolitis requiring surgery 2 noract_neo_gastro ___ 2 Spontaneous intestinal perforation requiring surgery 3 noract_neo_gastro ___ 3 None	Medical records.	Check only if confirmed and requiring surgical intervention.

NEONATAL

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Data variable	Field Label	Options	Data source	Description
[noract_neo_resp]	Was the baby in need of respiratory support Time frame: From birth - four weeks after due date	1 Yes 2 No	Medical records.	Covers both mechanical ventilation and non-invasive ventilation. Time frame: From birth to 4 weeks after expected due date
[noract_neo_rds]	Did the baby suffer from respiratory distress syndrome requiring surfactant treatment within first two days of life.	1 Yes 2 No	Medical records.	Mark if the baby was treated with surfactant within the first 48 hours of life.
[noract_neo_ab]	Did the baby have an early onset infection?	1 Yes 2 No	Medical records.	Definition: >5 days of antibiotics where the treatment starts within the first week after delivery
[neonatal_complete]	Section Header: Form Status Complete?	0 Incomplete 1 Unverified 2 Complete	Medical records.	Mark as complete.

SERIOUS EVENTS This form can be accessed any time during the trial from time of randomisation to 42 days after end of pregnancy and must be used to report any SAEs If you have any questions, please contact: lea.hansen@clin.au.dk				
Data variable	Field Label	Options	Data source	Description
[ser_info]	In this form you will enter data on serious events/harm to the mother throughout the trial and until 42 days after birth or miscarriage			
[noract_mat_death]	Maternal death	1 Yes 2 No	Medical records.	Did the participant die from time of randomisation to 42 days after delivery? Timeframe: From enrollment to 42 days of delivery
[noract_death_cause]	Please state the cause of death	Free text	Medical records.	If yes to maternal dead, state cause of dead as written in the medical notes.
[noract_mat_icu]	Was the participant admitted to ICU from time of randomisation to 42 days after delivery? Timeframe: From enrollment to 42 days of delivery	1 Yes 2 No	Medical records.	ICE admission from any cause.
[noract_ice_cause]	Please note the reason for ICU admission	Free text	Medical records.	
[noract_thrombosis]	Did the participant have any thromboembolic events	1 Yes 2 No	Medical records.	Defined as deep vein thrombosis, pulmonary embolism or stroke from time of randomisation to 42 days after delivery? Time frame: From procedure to 42 days of delivery