NORACT BOARD
Mandate

Version 2,0
Prepared by Lea Kirstine Hansen 230607
Approved by the NORACT Board 230613

CONTENTS

AIM

The NORACT Board ensures feasibility and endorsement across the participating countries in the NORACT trial.

RESPONSIBILITIES AND TASKS[1, 2, 3]

	The NORACT BOARD	The TSC
Prior to start of trial	Finalize and endorse the NORACT Board mandate, the Independent Data Monitoring Committee (IDMC) and Trial Steering Committee (TCS) charters and the organization of the trial. Suggest and agree on members of the IDMC and TCS. Finalise major, scientific aspects of the protocol. Finalise the data monitoring plan and monitoring of data quality across all countries and sites. Approve the eCFR. Agree on the statistical analysis plan. Approve the website. Endorse the publication policy.	Approve TSC charter Approve Trial Protocol Sanctioning and/or proposing protocol changes Approve the statistical analysis plan
During trial period	Provide supervision for the trial within each country though the National Coordinating Investigators. Evaluate reports from TSC. Overall responsibility for quality assurance on control and intervention.	Evaluate data from the internal pilot and decide how to proceed with the full trial. Overall responsibility for the scientific integrity and conduct of the NORACT trial. Decisions regarding: - Early stopping due, for example, to clear benefit or harm of a treatment, futility, or external evidence - Stopping recruitment within a subgroup

		- Extending recruitment (based on actual control arm response rates being different to predicted rather than on emerging differences) or extending follow-up
After trial has ended	Participate in the writing process of the main trial publication. Expected writing process: 1. First and last author (Lea Kirstine Hansen and Julie Glavind) Prepares data for discussion in the NORACT Board. 2. First drafts circulated to Board members. 3. Subsequent drafts discussed in the Board. 4. Final draft circulated to all authors	
Studies using data registered or collected as part of NORACT	Evaluate and approve study proposals from investigators inside or outside the NORACT group. The NORACT PhD study as described from the original study proposal is given priority to be published, until further studies with overlapping aims can be planned. Study proposals from investigators inside or outside the NORACT collaboration are send to the NORACT Board (please use the NORACT study proposal form) for approval. All legal and ethical approvals must be available before data can be accessed.	

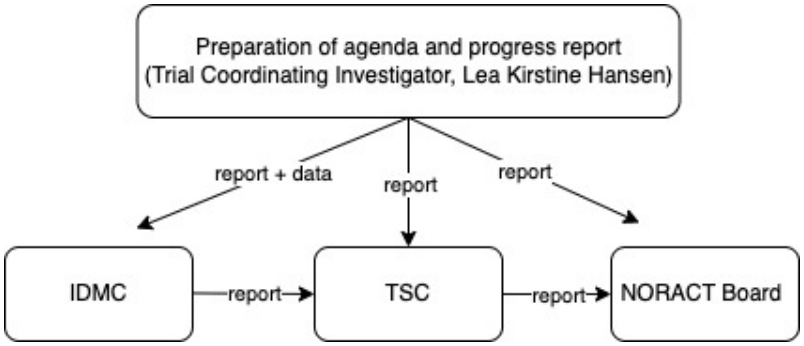
DECISION MAKING

The Board is decisive but respects that final responsibility lies within the Sponsor (Niels Uldbjerg) and the Trial Steering Committee.
Effort should be made for all members to attend the meetings. If a member is unable to attend, this member can pass any comments to the agenda prior to the meeting, for consideration during the discussions.
Every effort should be made for the NORACT Board to reach a unanimous decision. If the board cannot achieve this, a vote may be taken, although details of the vote should not be routinely included in the decision making.

MEETING ORDER

1. IDMC
2. TSC
3. NORACT Board

The meeting following the TCS meeting will be held annually. The board will decide whether the meeting is virtual or face-to-face in one of the collaborating countries.
Meetings outside the above-mentioned schedule will be ad hoc with regular intervals according to the needs and demands of the trial management group.
Niels Uldbjerg is responsible for scheduling the meetings.



MEMBERS

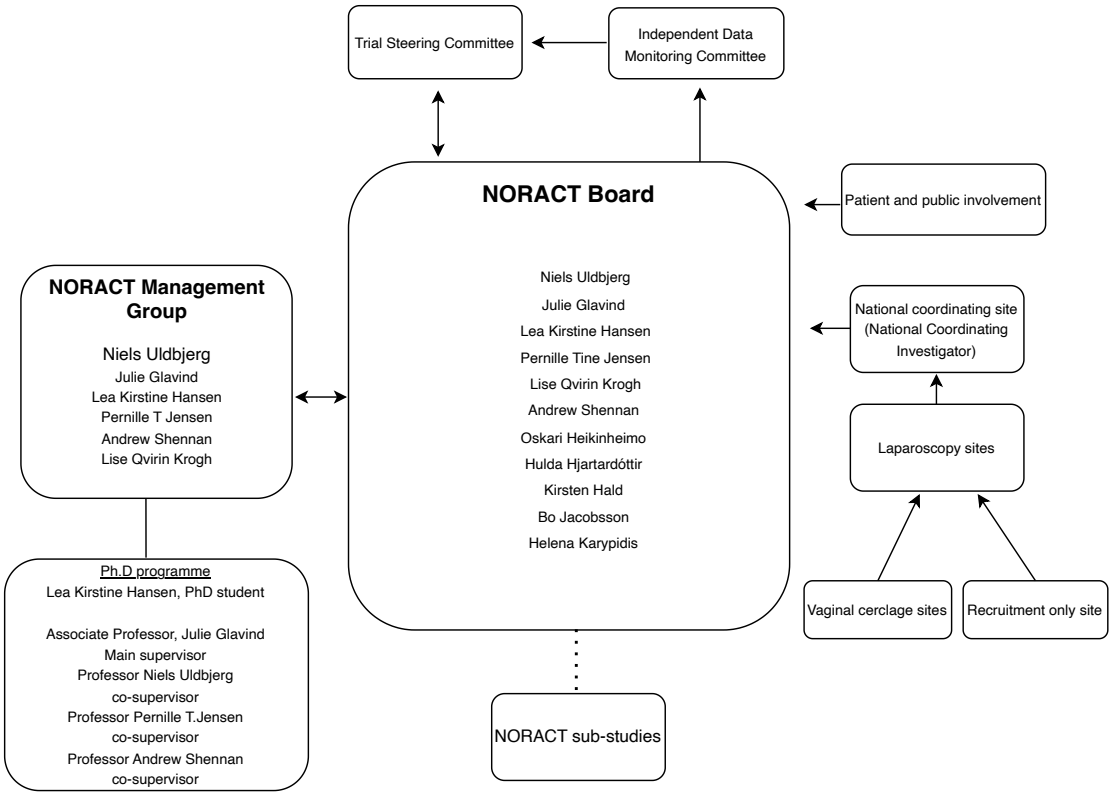
New members or replacement of members who wish to resign from the board will be discussed within the NORACT Board.

Members of the NORACT Board

- Niels Uldbjerg, Sponsor, chair
- Julie Glavind, Principal Investigator
- Lea Kirstine Hansen
- Lise Qvirin Krogh
- Pernille Tine Jensen
- Bo Jacobsson
- Helena Karypidis
- Hulda Hjartardóttir
- Kirsten Hald

- Oskari Heikinheimo
- Andrew Shennan

ORGANISATION OF THE TRIAL



TITLES	
Sponsor	Niels Uldbjerg, Aarhus University Hospital
Principal Investigator (PI)	Julie Glavind
Trial Coordinating Investigator	Lea Kirstine Hansen
National Coordinating Investigators	Oskari Heikinheimo Kirsten Hald

	Hulda Hjartardóttir Helena Karypidis Andrew Shennan
Site Investigators	One at each site (Laparoscopy, Vaginal or recruitment only)
NORACT BOARD (Former Trial Steering Group)	
Julie Glavind Lea Kirstine Hansen Lise Qvirin Krogh Niels Uldbjerg (Chair) Pernille Tine Jensen Andrew Shennan Bo Jacobsson Helena Karypidis Hulda Hjartardóttir Kirsten Hald Oskari Heikinheimo	
NORACT MANAGEMENT GROUP	
Niels Uldbjerg Julie Glavind Lea Kirstine Hansen Pernille T Jensen Andrew Shennan Lise Qvirin Krogh	
NORACT Independent Data Monitoring Committee (IDMC)	
Paul Seed (UK), (chair) – to be confirmed Verena Sengpiel (SE) Victoria Hodgetts Morton (UK)	

NORACT Trial Steering Committee (TSC)
Nigel Simpson (UK), (chair) Caroline Fox (UK) A neonatologist – to be appointed Julie Glavind (DK) Niels Uldbjerg (non-voting) Lea Kirstine Hansen (non-voting)

NORACT STUDY PROPOSAL FORM

Please send all proposals to auh.noract@rm.dk

All proposals are discussing in the NORACT steering group.

Only Word-files with full project title and name of the submitter are accepted.

Submission date (YYYY-MM-DD): NORACT PI: Co-PI (outside NORACT): E-mail: Affiliation(s): International partners: Phone number:	
Full title of proposed study	
Study group members	
Study summary	
Background (brief)	
Overall objective of project	
Study design and analysis plan	
Data required	
Outcome	
Timeline	

Start date	
End date:	
Funding:	
Ethics:	
Approval / rejection date:	

REFERENCES

1. Harman NL, Conroy EJ, Lewis SC, Murray G, Norrie J, Sydes MR, et al. Exploring the role and function of trial steering committees: results of an expert panel meeting. Trials. 2015;16:597.
2. Damocles Study Group NHSHTAP. A proposed charter for clinical trial data monitoring committees: helping them to do their job well. Lancet. 2005;365(9460):711-22.
3. NIHR. Research Governance Guidelines https://www.nihr.ac.uk/documents/research-governance-guidelines/12154?pr=htmlfile%5CShell%5COpen%5CCommand2022 [