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Nordic randomised trial on laparoscopic versus vaginal cerclage (NORACT): trial protocol for an international, multicentre, randomised controlled trial

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ABSTRACT

Introduction Transvaginal and transabdominal cerclage procedures have become established interventions to prevent mid-trimester pregnancy loss and preterm birth. Transabdominal cerclage seems to be superior to transvaginal cerclage in women with a history of a failed transvaginal cerclage. However, with the availability of a less invasive laparoscopic procedure, there is limited evidence concerning which type of cerclage to recommend to many other risk groups. The objective of this trial is to compare laparoscopic abdominal cerclage and transvaginal cerclage in women at moderate to high risk of spontaneous preterm birth.

Methods and analysis The trial is an open, multicentre, superiority, parallel arm randomised controlled investigator-initiated trial with an embedded internal pilot. Women in whom the clinician has clinical equipoise between laparoscopic and transvaginal cerclage are randomised to either laparoscopic abdominal or transvaginal cerclage in a ratio of 1:1. The trial extends from sites in Denmark, Finland and Norway. The primary outcome is birth <32 weeks of gestation. A total sample of 188 participants will be included to detect an absolute difference of 15% in the primary outcome between the two groups. Analysis will be by intention-to-treat.

Ethics and dissemination The Central Denmark Region Committee on Biomedical Research Ethics, Denmark, Helsinki University Hospital Ethics committee, Finland and the Regional Committees for Medical and Health Research Ethics, Norway approved the trial. This protocol is published prior to complete data collection and analysis. Important protocol changes will be made publicly available on ClinicalTrials.org, on the trial website and distributed electronically to all active sites. Positive, inconclusive as well as negative results from the trial will be published in peer-reviewed international scientific journals.

Trial registration number NCT06122506.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ An embedded internal pilot trial to assess feasibility, recruitment and acceptability.
- ⇒ Comprehensive outcome measures, reflecting core outcome sets, will ensure a robust evaluation of interventions.
- ⇒ The broad eligibility criteria will require sensitivity analyses to address individual risk factors.
- ⇒ Blinding was not possible.

INTRODUCTION

Preterm birth (PTB) is a major cause of neonatal death and serious lifelong disabilities.[1 2] The aetiology is complex and multifactorial.[3] Some women at high risk of PTB can benefit from cervical cerclage.[4 5] This can be applied transvaginally or transabdominally, with the latter applied by laparoscopic or open access surgery. The laparoscopic procedures are less invasive and associated with better recovery and likely to be more acceptable than open procedures.[6] Despite over half a century of clinical use, there is only limited evidence evaluating which women will benefit from which type of cerclage modality.[4 7 8] Randomised controlled trials (RCTs) on cerclages are challenging and limited and rarely take risk factors into account or evaluate meaningful outcomes.[4 9 10] The multicenter randomised controlled trial of transabdominal vs transvaginal cervical cerclage (MAVRIC) remains the only RCT comparing transabdominal cerclage (TAC) to transvaginal cerclage (TVC).[11] In this study, women with a previous failed vaginal cerclage were assigned to either open TAC or a TVC. The participants in MAVRIC covered a broad range of obstetric risk factors such as previous PTB, uterine anomaly, history of cervical surgery or one or more mid-trimester losses. Despite this heterogeneity, the MAVRIC study demonstrated that open TAC was consistently effective, regardless of the preceding

Box 1 Predefined risk groups for inclusion and subgroup analysis

- ⇒ Participants with a history of emergency/labouring caesarean section followed by a spontaneous singleton late miscarriage or preterm birth 14+0 to 28+0 weeks.
- ⇒ Participants with a prior elective vaginal cerclage placement but nonetheless a spontaneous late miscarriage or preterm birth between 14+0 and 28+0 weeks
- ⇒ History of a prior emergency cerclage with delivery between 14+0 and 28+0 weeks
- ⇒ Participants with a history of one or more deliveries between gestational age 16+0 to 28+0 and a clinical diagnosis of cervical insufficiency.
- ⇒ Any conisation and a short pre-pregnancy cervix (eg, short ectocervix with inspection or below 15–20 mm with ultrasound)
- ⇒ History of three or more deliveries with gestational age 16+0 to 36+6 weeks.

obstetrical history. Evidence from cohort studies on laparoscopic cerclage (lapTAC) shows favourable obstetrical outcomes in various indications.[12–15] Women in these cohorts have different risk profiles, including nullips with cervical surgery or with one or two mid-trimester losses. Accordingly, lapTACs are being offered to women, where there is uncertainty about their indication and efficacy compared with TVCs in other indications than a failed TVC.[11]

To fill this evidence gap, we have designed an RCT to compare in women with varying risk factors lapTAC and TVC on the risk of birth before 32 weeks of gestation.

METHODS AND ANALYSIS

The trial will include an embedded internal pilot trial to investigate the feasibility.

Objectives

The primary objective of the main trial is to compare lapTAC with TVC on preventing PTB before 32 weeks of gestation and on baby death in women at risk of PTB where the clinician has equipoise as to which treatment is better. The objective of the embedded pilot trial is to describe the rate of participant inclusion, the feasibility and acceptance of the interventions and the type of participants included (see box 1 for examples of patient categories). The secondary objective is to assess the effect of surgical method on maternal and neonatal outcomes.

Trial design

The Nordic randomised trial on laparoscopic versus vaginal cerclage (NORACT) is an open-label, multicentre, superiority, parallel arm, randomised controlled, investigator-initiated trial with an embedded internal pilot trial.[16–18] At the end of the internal pilot trial, the above-mentioned objectives will be assessed, while all outcome data collected during the internal pilot trial will be analysed at the end of the full trial. The internal pilot will allow testing the progress of the collaborations, since some sites have limited experience with the tested procedures, and in particular, because of the uncertainties with availability of eligible patients and the ability to recruit patients.[19]

Participants will be randomised in a 1:1 ratio in permuted blocks of 4, 6 and 8 to either lapTAC or TVC with stratification according to country.

Study setting

The study extends from sites in Denmark, Finland and Norway. The study can be expanded to other countries on obtained ethical and legal approvals. Each country will have one or more sites where vaginal and/or laparoscopic cerclages are performed to ensure that women from all parts of the countries can be referred for an eligibility evaluation. Information and randomisation are centralised at the laparoscopic sites, that is, sites that perform lapTAC. The study duration is estimated to be 5 years, and the recruitment period will end on 1 January 2028, unless a prolongation has been suggested and accepted by the Trial Steering Committee (TSC) and the board.

Organisation

A board was established including investigators from all participating countries. The daily management of the trial is handled by a smaller management group. Three independent members have been appointed to a TSC and another three independent members have been appointed to an Independent Data Monitoring Committee (IDMC) prior to commencement of the trial. Charters describing the roles and responsibilities of the IDMC and the TSC, including the timing of meetings, methods of providing information between the IDMC and the TSC, frequency and format of meetings, statistical issues and relationships with other committees were approved by the board and the IDMC and TSC members and signed prior to recruitment start.

Participants

Women at risk of PTB are eligible to participate in the trial before they become pregnant or in early pregnancy of less than 10 weeks of gestation, if their clinician is in equipoise between lapTAC and TVC to prevent PTB. Any circumstance under which the clinician is not willing to randomise is an exclusion criterion. This criterion includes any condition or circumstance under which laparoscopic or vaginal cerclage surgery is contraindicated (ie, on-going pregnancy of more than 10 weeks of gestation). As the majority of participants are recruited pre-pregnancy, multiple pregnancies will not be excluded post-randomisation. To support clinicians, box 1 lists examples of women who could be considered for participation in the trial. See figure 1 for trial flow chart.

Identification

Eligible women will be counselled by a consultant either during a pre-pregnancy consultation or appropriate clinic. In addition, participants can opt for participation

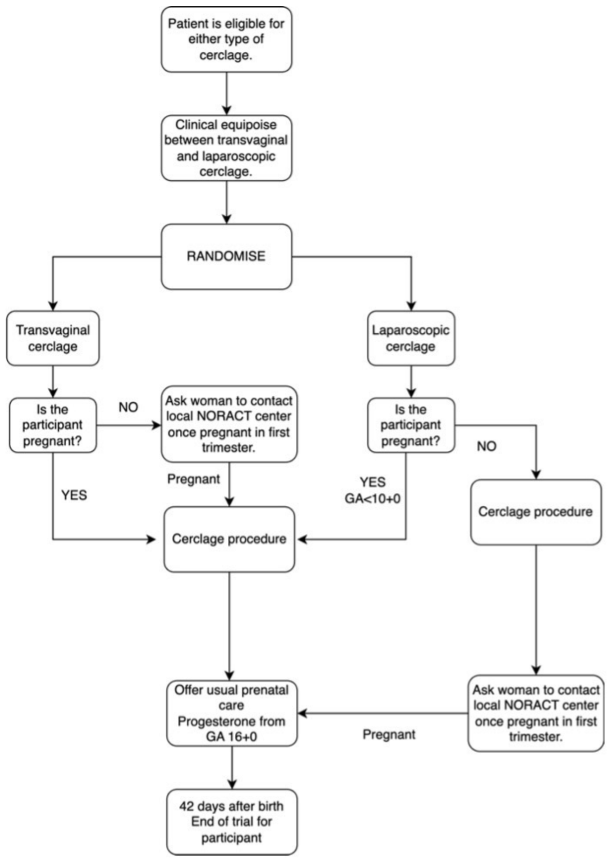

Figure 1 Trial flow. GA, gestational age; NORACT, Nordic randomised trial on laparoscopic versus vaginal cerclage.

through posters, handouts and spreads at social media platforms (ie, online support groups) where applicable.

Information

Both verbal and written information will be centralised to laparoscopic trial sites in each country. When a potential participant is identified and referred, she is booked for a consultation at the nearest laparoscopic site. The verbal information is given by one of the responsible physician investigators or from another assigned research staff member at the laparoscopic site.

Consent is obtained prior to randomisation. The consent form is either digital using secure email and Research Electronic Data Capture (REDCap) which has dedicated functionalities for written consent that are in accordance with the law of data protection or in paper, depending on the preference of the individual country.[20]

Decliners

Women who decline participation in the trial are asked to sign a separate consent form agreeing to share data on their birthdate, body mass index, obstetrical history (ie, number, delivery mode, interventions and gestational age with previous deliveries), previous conisation, current clinical findings (cervical length by inspection and ultrasound), their stated reason for declining participation in the trial and their delivery outcomes. This information is collected for the purpose of assessing the internal validity and the generalisability of the trial and to estimate trial feasibility.

Intervention: laparoscopic cerclage

Anaesthesia: general.

Timing: pre-pregnancy or up till 10 weeks of gestation.

Surgical access: conventional laparoscopy or robot-assisted laparoscopy.

Procedure: a manipulator is applied to the non-pregnant uterus according to local routine. In the case of an ongoing pregnancy, no uterine manipulator is used. Detachment of the bladder peritoneum and bladder, and dissection of the uterine arteries are performed at the surgeon's discretion. Non-absorbable woven band or sutures 0-1-2 are used for the cerclage according to local routine. The cerclage suture is placed in the cervico-corporal angle medial to the uterine arteries. The suture is placed by the Endo Close needle technique[14] or by the Deschamps needle technique[21] with anterior or posterior knots according to local routine. An armed suture or band[15 22] can be used at the surgeon's discretion.

Surgical proficiency: the laparoscopic cerclage procedures must be performed by appropriately experienced laparoscopic surgeons at consultant level. Prior to recruitment start at each site, a standardised quality assurance on laparoscopic cerclage procedures is conducted by a group of proctors appointed by the board. Each laparoscopic surgeon is certified by the same proctors using video-taped recordings of one or two procedures.

Comparison: transvaginal cerclage

Anaesthesia: regional or general.

Timing: during pregnancy; from identification of fetal heart rate activity up to 16 weeks of gestation. Procedure: lithotomy position. The needle is passed through the collum substance and mucosa four to eight times in a purse string, in the upper portion of the vaginal cervix, and must include sufficient tissue to avoid tearing out. Penetration of the cervical canal should be avoided. Choice of suture material is at the discretion of the surgeon.[23] The suture is placed ad modum McDonald (low) 'as high as possible'.[24] If necessary, a Shirodkar (high) procedure is acceptable, where the bladder is mobilised, as an intra-operative decision. A second suture can be applied if this can be placed in a more cranial position than the first suture.

Surgical proficiency: the TVC surgeons must be at consultant level or experienced with performing the procedure as a primary surgeon.

Common pathway for intervention and comparison arms

Antibiotics and tocolysis: at the discretion of the surgeon.

Progesterone: vaginal progesterone 200 mg daily from week 16–18 to 34 weeks of gestation is recommended. Local guidelines will be accepted.

Bed rest: not routinely recommended.

Physical relief and sick leave: at the discretion of the surgeon.

Intercourse: not contraindicated.

Definition of adherence

Adherence to the allocated intervention will be monitored. In this trial, adherent participants are those randomised to lapTAC, who receive a lapTAC prior to 10 weeks of gestation and those randomised to TVC, who receive a TVC prior to 16 weeks of gestation. A subsequent emergency TVC will count as adherence. Data from adherent participants will form the per-protocol (adherence) analysis.

Sample size calculation

The primary outcome is birth before 32 weeks of gestation (binary). The sample size is based on a target difference of 15% (20% in the TVC group vs 5% in the lapTAC group). This effect size was estimated based on the rate of birth before 32 weeks of gestation in the MAVRIC study (33% in the TVC group vs 8% in the TAC group).[11] Due to the difference in inclusion criteria, the participants in NORACT are likely to have a somewhat lower risk of PTB compared with the MAVRIC study, leading to an assumed baseline event rate of 20% with the TVC and 5% with lapTAC (alpha 0.05 and power of 80%). This magnitude of target difference was determined to be clinically important as well as realistic. We inflated for 10% attrition (for those who do not become pregnant or have an early loss) and a further 10% loss to follow-up resulting in a total of 188 women (94 in each group).

For the outcome baby death, the proportions from the MAVRIC study were 21% in the TVC group versus 3% with TAC.[11] Expecting a slightly lower PTB risk in our population and with a sample size of 188 participants, we have a power of 80 to detect a target difference of 15%.

Given the uncertainty of the event rate in our sample population, it was agreed that the IDMC would monitor the pooled event rate throughout the trial to assess the need to prolong the recruitment period and thereby increase the sample size.

Outcomes

Primary clinical outcome

There are two prioritised outcomes based on a conditional hierarchical approach in the following order:

Birth <32 weeks of gestation (definition: in the first viable pregnancy beyond 14 weeks of gestation).

Baby death (defined as loss of a viable pregnancy beyond 14 weeks of gestation, stillbirth, late miscarriage or death of a live born infant within 28 days from date of birth or miscarriage).

For secondary outcomes, see online supplemental file 1.

Data collection

Data will be collected in a REDCap electronic case report form (eCRF), where almost every response is pre-coded. The randomisation programme is embedded in REDCap and will automatically transfer the entry data to the eCRF in REDCap. The responsible physician investigator or an assigned and educated research staff member from the local clinical team is responsible for data collection and entry. A detailed data dictionary that clearly defines all included variables was created prior to patient enrolment and is available at the trial website.[25]

If participants discontinue or their care deviates from the intervention protocols, we will continue to collect data, unless the woman specifically states that we cannot collect or store her data. The responsible investigator or an assigned and educated research staff member from the local clinical team will be responsible for data collection and entry.

Internal pilot trial

After a 24-month inclusion period, the data monitoring committee will evaluate data from the internal pilot and make recommendations for the future course of the trial. The possible recommendations after the pilot trial can be (1) continue with no changes, (2) continue with limitations to the inclusion criteria (ie, certain subgroups of women are excluded from the trial) or (3) not to continue with the full trial. The evaluation will be based on relevant items from the acceptance checklist for clinical effectiveness pilot trials (ACCEPT) checklist.[17]

The trial sites will continue recruitment during the evaluation period of the pilot trial.

Presentation of the quantitative data from the internal pilot will largely consist of descriptive statistics and comparisons between the two groups. The inclusion number will be described according to country, site and groups in box 1. No outcome data will be available for evaluation.

Statistical analysis plan

The objective of this trial is to test the superiority of one intervention to another. The null hypothesis is that there is no difference in the rate of PTB before 32 weeks of gestation between women allocated to lapTAC versus TVC. The alternative hypothesis is that there is a difference between the groups.

For the primary outcome of PTB, a p value will be produced, with statistical significance considered at the 5% level. For the second prioritised primary outcome of baby death, we will incorporate a conditional hierarchical approach to hypothesis testing to ensure we appropriately control for the overall rate of type I error.[26] If the primary outcome of PTB meets a superiority conclusion in favour of either lapTAC or TVC, we will then proceed to examine any differences between the two procedures for baby death. If the p value from this test (baby death) is less than or equal to 0.05 in the model (or if the 95% CI does not contain the value 1) we will declare superiority for this outcome. Secondary outcomes will be considered as exploratory; no adjustment for multiple comparisons will be made and hence significance should not be inferred from the CI width.

All primary analyses (primary and secondary outcomes) will be conducted on a modified intention-to-treat basis

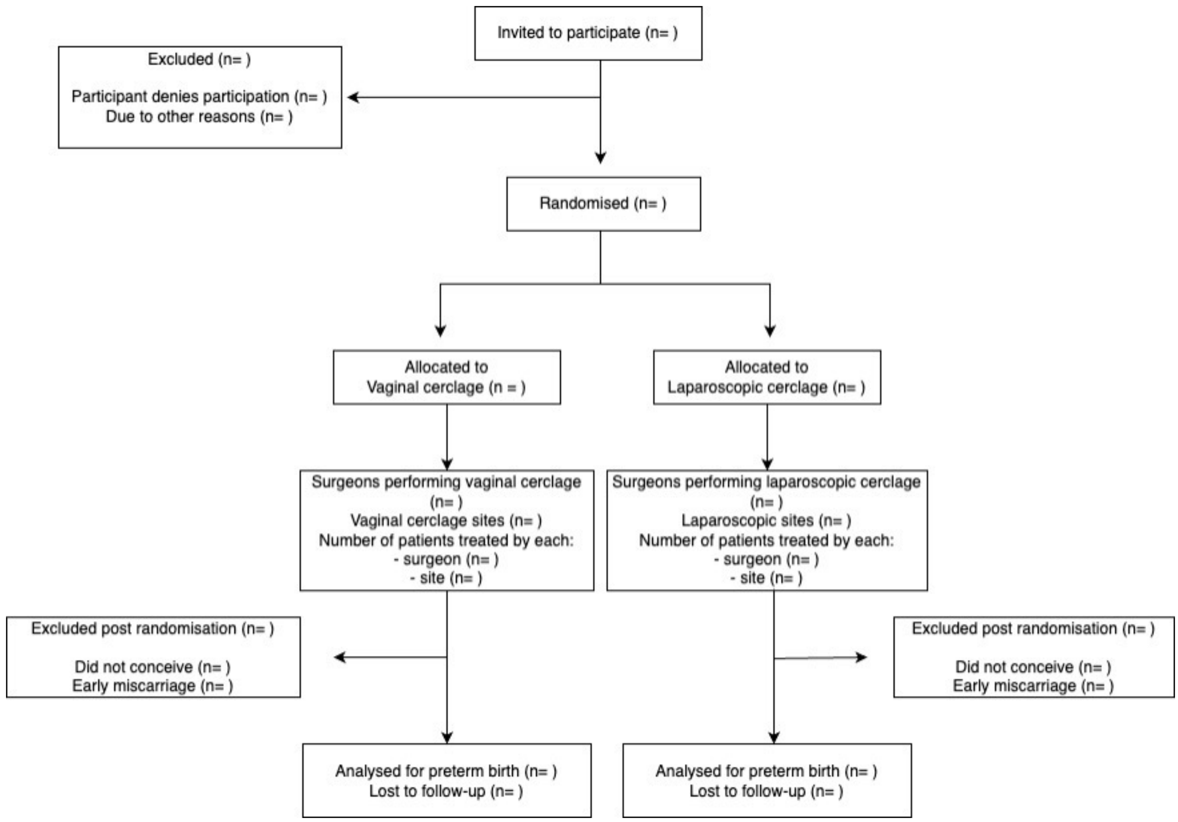

Figure 2 Consolidated Standards of Reporting Trials flow diagram of the Nordic randomised trial on laparoscopic versus vaginal cerclage trial.

only including patients who are pregnant at time of randomisation or become pregnant after randomisation and carry a pregnancy beyond 14 weeks. Participants who have an early miscarriage will be excluded post-randomisation, unless they have a viable pregnancy beyond 14 weeks later in the trial period. The rationale behind this decision is that an early miscarriage is unlikely to be caused by a short cervix. If a participant has more than one pregnancy above 14 weeks only the first pregnancy post-randomisation will provide data for the final analysis. Participants will be analysed in the intervention group to which they were randomised, and all participants shall be included whether they received the allocated intervention or not.

A secondary per-protocol and as-treated analyses will be performed for each treatment group for the primary outcomes only.

Subgroup analyses will be conducted to determine whether there are signs of an effect for each prespecified subgroup. To ensure validity to the subgroup analysis, the populations considered for subgroup analyses are prespecified in box 1.

The statistical analyses and reporting will adhere to the Consolidated Standards of Reporting Trials (CONSORT)-guidelines.[27 28]

'R' will be used for data management and analyses. Patient inclusion and exclusion will be illustrated in a modified CONSORT flow diagram for non-pharmacological trials[29] (see figure 2). The full analysis plan is available at ClinicalTrials.org (registration ID NCT06122506) and on the trial website.[25]

Monitoring and oversight

The trial is monitored according to Good Clinical Practice (GCP) standards. A decision as to perform an interim analysis will be made after the internal pilot period. The IDMC will evaluate pilot data after 24 months of inclusion. In the full trial, there will be no predefined stopping criteria, and criteria for termination will be at the discretion of the TSC and the trial sponsor.

Participants enrolled in the NORACT trial will follow local guidelines for clinical follow-up. Alerts of serious adverse events (SAEs) will be integrated in REDCap to notify the trial coordinating investigator and the principal investigator when an SAE is registered.

For data integrity, the primary outcome will be validated after inclusion of the first 85 participants and at the end of data collection for the full trial.

The data analysts will be blinded to the interventions.

Harms and benefits

The inherent risks of complications from pregnancy and birth exist regardless of the conduct of this trial.

The lapTAC is performed under general anaesthesia, the intervention is a placement of a permanent suture material and the woman can only deliver by a caesarean section. Further, since the operation is performed prior to or in very early pregnancy, there is a risk of the procedure being futile or that the band needs removal (with the operative risks associated herewith) if the woman miscarries at a gestation beyond 14 weeks or never conceives. There is a small risk of bleeding, harm to adjacent organs or infection. The lapTAC may, to a higher extent, prevent PTB in selected groups of women.

The TVC needs to be performed in each new pregnancy but otherwise has limited harms. It may prevent PTB to a lower extent in selected groups of women. There is a small risk of pain, bleeding and infection. The TVC is rarely futile as the operation is performed during pregnancy, it is performed in regional anaesthesia and it is removed by a relatively simple procedure close to term to allow for vaginal birth.

The risk of complications from the two procedures is no different from when the procedures are carried out in the normal clinical handling of the patients. In the women, a lapTAC and a subsequent caesarean section may carry more operative risks than a TVC and a vaginal birth. However, if a lapTAC proves more effective in preventing PTB than a TVC, this could outweigh these risks.

The following events are regarded as SAEs:

Any untoward and unexpected medical occurrence or effect that:

- Results in maternal death.
- Is life-threatening, that is, refers to an event in which the subject was at risk of death at the time of the event.
- Results in an unexpected hospitalisation, or prolongation of pre-existing hospitalisation.
- Results in persistent or significant disability or incapacity.

The following are not considered adverse event (AE) or SAEs:

- Admissions or outpatient attendance for common pregnancy conditions, for example, fetal monitoring, maternal hypertension, antepartum haemorrhage, abdominal pain, non-cephalic presentation, placenta previa.
- Outpatient attendance for common complications from the cerclage procedures, for example, infections and bleeding from the insertions.
- Hospitalisation for vaginal cerclage removal, preterm labour, labour, induction of labour, caesarean section, elective treatment for pre-existing conditions.
- Admission for common postpartum problems, for example, maternal hypertension, perineal complications, urinary tract complications, breastfeeding challenges, mental health problems and puerperal infections.

All AEs will be recorded. Regarding SAE, an SAE form will be completed by the responsible physician investigator and sent to the principal investigator and trial sponsor within 24 hours from when the event is known. The SAE will be assessed by the NORACT board and reported to the IDMC individually and at IDMC meetings in summarised form. Assessment of the SAE will be based on available laboratory values and clinical data. If related to any drug administrated as part of the intervention, the summary of product characteristics will be included in the assessment of causality and expectedness of the event.

Patient and public involvement

Prior to recruitment start, the trial protocol, website and patient information leaflet were presented to a patient panel on PTB. Participants in the patient panel were presented with the trial material before an online meeting with discussion about the trial. Feedback from the participants was used to modify the protocol and patient information.

ETHICS AND DISSEMINATION

The trial will be conducted in accordance with the ethical principles outlined in the latest version of the 'Declaration of Helsinki' and the 'Guideline for GCP' related to experiments on humans. The trial is approved by the Central Denmark Region Committee on Biomedical Research Ethics approved the trial (registration number: 1-10-72-24-23), the Helsinki University Hospital Ethics Committee, Finland (registration number: HUS/567/2024) and the Regional Committees for Medical and Health Research Ethics, Norway (registration number: 608896). The results of the trial will be reported according to the CONSORT 2010 statement.[29] Important protocol changes will be made publicly available on ClinicalTrials.org, on the trial website and distributed electronically to all active sites. Positive, inconclusive as well as negative results from the trial will be published in peer-reviewed international scientific journals. The results of this trial have the potential to generate important knowledge for the improvement of PTB and the potential to lower the mortality and morbidity caused by PTB in future high-risk pregnancies.

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Contributors LKH, NU and JG drafted the initial version of the protocol and secured funding, with OH, KH and BJ as co-applicants. Further development of the trial protocol and conceptualisation of the trial was led by JG, the principal investigator, in collaboration with all authors. The daily management of the trial is led by LKH, who also drafted the manuscript. All authors have read and approved the manuscript. LKH is the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement The final trial dataset will be available upon reasonable request from the principal investigator after publication of the main trial results. Data sharing will be in accordance with applicable legal requirements and ethical guidelines.

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REFERENCES

1 Patel RM, Kandefer S, Walsh MC, *et al*. Causes and timing of death in extremely premature infants from 2000 through 2011. *N Engl J Med* 2015;372:331–40.
2 Gruending A, Lawn JE, Reid A, *et al*. Born Too Soon: learning from the past to accelerate action in the next decade. *Reprod Health* 2025;22.
3 Goldenberg RL, Culhane JF, Iams JD, *et al*. Epidemiology and causes of preterm birth. *Lancet* 2008;371:75–84.
4 Story L, Shennan A. Cervical cerclage: an evolving evidence base. *BJOG* 2024;131:1579–86.
5 Wennerholm U-B, Bergman L, Kuusela P, *et al*. Progesterone, cerclage, pessary, or acetylsalicylic acid for prevention of preterm birth in singleton and multifetal pregnancies - a systematic review and meta-analyses. *Front Med (Lausanne)* 2023;10.
6 Hulshoff CC, Hofstede A, Inthout J, *et al*. The effectiveness of transabdominal cerclage placement via laparoscopy or laparotomy: a systematic review and meta-analysis. *Am J Obstet Gynecol MFM* 2023;5:100757.
7 Benson RC, Durfee RB. Transabdominal cervico uterine cerclage during pregnancy for the treatment of cervical incompetency. *Obstet Gynecol* 1965;25:145–55.
8 MCDONALD IA. Suture of the cervix for inevitable miscarriage. *J Obstet Gynaecol Br Emp* 1957;64:346–50.
9 Rush RW, Isaacs S, McPherson K, *et al*. A randomized controlled trial of cervical cerclage in women at high risk of spontaneous preterm delivery. *Br J Obstet Gynaecol* 1984;91:724–30.
10 Lazar P, Gueguen S, Dreyfus J, *et al*. Multicentred controlled trial of cervical cerclage in women at moderate risk of preterm delivery. *Br J Obstet Gynaecol* 1984;91:731–5.
11 Shennan A, Chandiramani M, Bennett P, *et al*. MAVRIC: a multicenter randomized controlled trial of transabdominal vs transvaginal cervical cerclage. *Am J Obstet Gynecol* 2020;222:261.
12 Abdulrahman N, Burger NB, Hehenkamp WJK, *et al*. Favorable surgical and obstetrical outcomes in pre- and postconceptional laparoscopic abdominal cerclage: a large multicenter cohort study. *Am J Obstet Gynecol MFM* 2024;6:101227.
13 Ades A, Parghi S, Aref-Adib M. Laparoscopic transabdominal cerclage: outcomes of 121 pregnancies. *Aust N Z J Obstet Gynaecol* 2018;58:606–11.
14 Riiskjaer M, Petersen OB, Uldbjerg N, *et al*. Feasibility and clinical effects of laparoscopic abdominal cerclage: an observational study. *Acta Obstet Gynecol Scand* 2012;91:1314–8.
15 Clark NV, Einarsson JI. Laparoscopic abdominal cerclage: a highly effective option for refractory cervical insufficiency. *Fertil Steril* 2020;113:717–22.
16 Eldridge SM, Lancaster GA, Campbell MJ, *et al*. Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. *PLoS One* 2016;11.
17 Charlesworth G, Burnell K, Hoe J, *et al*. Acceptance checklist for clinical effectiveness pilot trials: a systematic approach. *BMC Med Res Methodol* 2013;13.
18 Rosala-Hallas A, Gamble C, Blazeby J, *et al*. A review of current practice in the design and assessment of internal pilots in UK NIHR clinical trials. *Trials* 2019;20.
19 Avery KNL, Williamson PR, Gamble C, *et al*. Informing efficient randomised controlled trials: exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open* 2017;7.
20 Hansen LK. Participant consent form. https://noract.dk/wp-content/uploads/2024/05/240507-Informed-consent_dk_engl.pdf.
21 Burger NB, van 't Hof EM, Huirne JAF. Removal of an abdominal cerclage by colpotomy: a novel and minimally invasive technique. *J Minim Invasive Gynecol* 2020;27:1636–9.
22 Whittle WL, Singh SS, Allen L, *et al*. Laparoscopic cervico-isthmic cerclage: surgical technique and obstetric outcomes. *Am J Obstet Gynecol* 2009;201:364.
23 Hodgetts Morton V, Toozs-Hobson P, Moakes CA, *et al*. Monofilament suture versus braided suture thread to improve pregnancy outcomes after vaginal cervical cerclage (C-STICH): a pragmatic randomised, controlled, phase 3, superiority trial. *Lancet* 2022;400:1426–36.
24 Cook JR, Chatfield S, Chandiramani M, *et al*. Cerclage position, cervical length and preterm delivery in women undergoing ultrasound indicated cervical cerclage: a retrospective cohort study. *PLoS One* 2017;12.
25 Nordic randomized trial on laparoscopic versus vaginal cerclage. 2023. Available: www.noract.dk
26 Dmitrienko A, D'Agostino RB, Huque MF. Key multiplicity issues in clinical drug development. *Stat Med* 2013;32:1079–111.
27 Schulz KF, Altman DG, Moher D, *et al*. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Obstet Gynecol* 2010;115:1063–70.
28 Moher D, Hopewell S, Schulz KF, *et al*. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol* 2010;63:e1–37.
29 Boutron I, Altman DG, Moher D, *et al*. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. *Ann Intern Med* 2017;167:40–7.