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BEWISE Protocol

Bed rest with a short cervix on preterm birth

Content BEWISE Protocol

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1. Title

Bed rest with a short cervix on preterm birth (BEWISE).

2. Trial sponsor and principal investigator

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3. Purpose

a. The study's problem statement, hypothesis, endpoints, and rationale

The overall aim of this study is to compare gestational age at birth in women with a short cervix who are prescribed activity restriction versus those who are not.

We hypothesize that no activity restriction (NAR) is non-inferior to activity restriction (AR) in preventing preterm birth in pregnant women with a short cervix, and that NAR may lead to higher physical activity levels, a lower risk of maternal depression, and that AR may lead to an irreversible decrease in bone mineral density.

With this study, we want to answer the following questions

a) Is NAR non-inferior to AR in prolonging pregnancy?

Does NAR compared to AR:

b) Increase overall physical activity levels?
c) Decrease the risk of maternal depression?
d) Reduce the risk of decreased in bone mineral density?

b. Brief literature review and reference list

Preterm birth (PTB) is birth < 37 weeks of gestation. PTB accounts for ~10% of all deliveries internationally (15 million babies per year) and is the main cause of neonatal death and serious lifelong disabilities [1]. Restricting the physical activity level of the pregnant woman has been one of several interventions to prevent PTB in women at risk [2].

PTB can result from a weak cervix [3, 4], often due to previous cervical surgery or physiological factors, leading to cervical shortening during pregnancy, measured using transvaginal ultrasound (TVU) [5, 6]. Cervical length screening is performed in women at increased risk of PTB or used as a diagnostic examination in women with symptoms of a short cervix or preterm labour.

The definition of activity restriction (AR) varies widely, from bed rest to limiting physical activity for one or more hours daily [7-9]. AR has long been used to prevent PTB [10]. A meta-analysis found a higher PTB rate with AR (12.8%) versus no activity restriction (NAR), (6.2%) (RR 2.07, 95% CI 1.15–3.73) [11]. However, the interventions (activity levels) in these studies were unmeasured [7, 12] and heterogenous [9, 13], and women in mid-trimesters of pregnancy (week 20 to 28) were poorly represented [11]. Additionally, confounding by indication is a concern, as women at higher risk of PTB would be more likely to be prescribed AR [7, 12].

AR is being used in Denmark without evidence to support its effectiveness [14], instead, emerging evidence has shown an increase in PTB with AR [7, 12, 14] and significant adverse maternal and fetal effects [15]. In a pilot prospective cohort study by Zemet et al [16] women (n=49) at high risk of preterm birth between 24 and 32 weeks of gestation, with a sonographic short cervix < 20 mm were assessed. The women were asked to wear smart band activity trackers continuously for at least one week and were given no specific recommendations on the level of physical activity. PTB occurred in 75% of participants, with a significantly lower median step count in those who delivered preterm, suggesting an inverse association between PTB risk and daily activity levels. Although limited by its small sample size, this is the only study to date that quantitatively assesses the association between physical activity and PTB using objective data. Its findings support the hypothesis that activity restriction does not prevent PTB in high-risk patients.

AR and Physical Activity

Danish pregnant women generally comply with AR recommendations [17]. While several international medical societies no longer recommend AR [18], AR is still part of our treatment regimes in Denmark. Here, activity restriction (AR) has been recommended to women with a cervix<25 mm and varies from a few hours daily rest to complete bed rest, depending on cervical length [19]. The regime can last weeks or months of pregnancy if prescribed in early gestations [20].

AR and Maternal Mental Health

Women with high-risk pregnancies on AR experience higher anxiety and depression than those with uncomplicated pregnancies [21].

AR and a decrease in bone mineral density

Bed rest immobilisation rapidly decreases bone mineral density (BMD) due to unloading of bone and thereby increased bone resorption. Changes in BMD can be detected already after 3 weeks of immobilisation [22, 23]. Moreover, pregnancy and subsequent lactation also decrease BMD [24, 25] due to a

decrease in estrogen levels during lactation and a demand for calcium mobilization from the skeleton of the pregnant women mediated by parathyroid hormone-related peptide.

4. Methods

The recommendation to restrict physical activity for pregnant women with a short cervix is about to be phased out of the Danish national guidelines. In this study, we will collect data from women before and after this change in clinical practice. The recommendation will be changed one region at a time following a stepped wedge design and according to Figure 1, where each Danish region will participate (numbers 1-4). After one year, all regions will have changed their practice from AR to NAR.

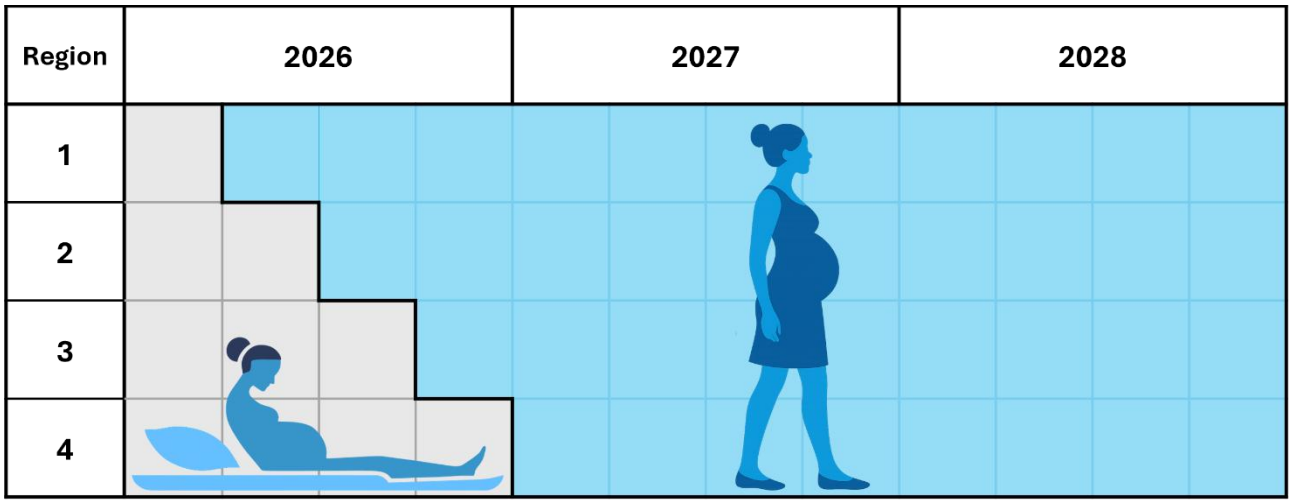

Figure 1 Grey fields: AR, blue fields: NAR

Study design

The study is a non-inferior stepped wedge cluster randomized controlled trial with embedded interrupted time-series.

The recommendation to use NAR or AR will be according to the stepped wedge implementation of the intervention and will not be based on consent from the participants in the study. In other words, we will change our national recommendations from using AR as part of the clinical PTB prevention protocol to not using AR in women with a short cervix in a stepped wedge design.

As part of the change in the clinical recommendations from AR to we wish to monitor the adherence to and outcomes of the new regime. Eligible participants will be asked to consent for the following:

All included participants (n=3.000):

1. Collection of data from electronic patient records.
2. Edinburgh Postnatal Depression Scale (EPDS) questionnaire [26, 27].

In subgroups of participants:

1. Collection of activity data based on SENS activity tracker in a subsample of 100 participants.
2. Blood samples in a subsample of 140 (70 from the AR and 70 from the NAR group).
3. DXA scans in subsample of 90 participants 12 months after the end of lactation.

Setting

All Danish birth centres.

Inclusion and exclusion criteria

Inclusion criteria

Pregnant women in gestational age 20+0 to 33+6 days with a short cervix, defined as less than 25 mm in singleton pregnancies and less than 30 mm in multiple pregnancies. Participants must be above 18 years of age and be able to read and understand Danish or English.

Exclusion Criteria

None.

Outcomes

Obstetric outcomes

- Gestational age at birth
- Number of days from inclusion to birth
- Onset of birth (spontaneous, induction or CS)
- Mode of birth
- Non-occipital presentation
- Interventions during birth
- Duration of birth
- Complications during birth
- Birth tear
- Maternal serious morbidity
- Umbilical cord pH
- Activity level during pregnancy and birth
- EPDS depression score
- Bone turnover marker levels
- DXA scan results

Neonatal outcomes

- Neonatal mortality
- Late miscarriage
- Fetal loss
- Birth weight
- Neonatal admission
- CNS morbidity
- Retinopathy of prematurity
- Gastrointestinal morbidity

- Respiratory support
- Respiratory distress syndrome
- Early onset infection
- Apgar score at 5 minutes
- Hypoglycaemia

Data Collection

Clinical data will be collected and managed using REDCap electronic data capture tools hosted at Aarhus University, Denmark [28]. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

All data collection of clinical variables follows the informed consent from the participants. Data will be collected by a research assistants from each region.

A data dictionary is developed prior to patient enrolment to ensure clear and consistent definitions of all included variables. It specifies each variable's name (including its corresponding database code), a detailed description, category options for categorical variables, and units and expected ranges for continuous variables. The data dictionary will be made publicly available.

1. **Prospective data**
   Prospective data on clinical variables will be collected by a research assistant in each hospital from the electronic patient record and registered in electronic standardized forms (eCFR) using REDCap. See section 8 for a full list of variables that will be collected.

2. **Activity data**
   Activity levels will be monitored using an activity tracker SENS (SENS motion® activity monitor, Copenhagen, Denmark; 45×21×5, 6 g) [29, 30]. Women with allergy to adhesive bandages will not be asked to wear SENS. Participants will be asked to wear SENS on their non-dominant thigh 24 hours a day from time of inclusion, until after birth, 100 participants. The device has a long battery life and is expected to function continuously for approximately four months. Twenty-four hours data will be collected on daily physical activity (i.e. no. of steps, prespecified activity events). The device is worn using a specially designed patch. The participants will not have access to their data.

3. **Mental health**
   Maternal depression will be evaluated using the Edinburgh Postnatal Depression Scale (EPDS) [26, 27] through electronic questionnaires 6-8 weeks post-partum. The questionnaires will be sent to the participants e-boks.

4. **Bone mineral density**

To investigate the effect of AR/NAR on BMD we will collect blood samples at baseline (time of inclusion) and after 4 and 8 weeks. In the blood samples we will measure bone turnover markers. 3 blood samples of 4 ml will be collected.

5. **DXA scans**
   12 months after the end of lactation we will measure BMD using dual-energy X-ray absorptiometry (DXA) in 90 participants of the participants in the immobilized group (cervix < 15 mm) and compare it to a reference population.

Deviations from standard treatment

All women in the study will receive standard antenatal care. This means that any prophylactic or therapeutic interventions during pregnancy relies on national or local clinical practice.

If results from DXA scans or blood samples give rise to further investigations, the woman will be referred for further evaluation, provided she indicated on the consent form that she wished to have this information.

After answering the EPDS questionnaire the participants will be contacted if the EPDS score is ≥ 11. If the score is ≥ 11 [26] she will be advised to contact her general practitioner for follow up.

5. Statistical considerations

This study is designed as a stepped-wedge cluster randomized trial evaluating the change in recommendations from using activity restriction to not using activity restriction to prevent preterm birth in women with a short cervix.

Since the study is designed around a practice change at cluster level, the sample size is not based on a conventional power calculation for a single primary outcome. Instead, the projected number of participants is determined pragmatically, based on feasibility and expected case numbers. In Denmark, approximately 2,300 women per year are anticipated to meet the inclusion criteria, corresponding to about 4% of the pregnant population. Over the full study period, we will potentially include around N = 6,000 women. This number is considered sufficient to provide meaningful evidence on maternal and neonatal outcomes within the stepped-wedge design.

We will assume a 25% variation in changes in bone markers (blood test). With 70 participants in each group, this will allow us to detect a difference of 12%. Therefore, a subgroup of approximately 140 women with a cervical length <15 mm will undergo serial blood sampling.

For bone mineral density (BMD), to detect a 3% difference with 80% power, a standard deviation of 10%, an alpha level of 5%, and an expected dropout rate of 20%, a total of 90 participants should undergo DXA scanning.

This large-scale data collection allows for the evaluation of multiple clinical and patient-reported outcomes with high generalizability. Statistical analyses will include appropriate adjustments for potential confounding factors such as gestational age at diagnosis, parity, prior preterm birth, and cervical length. A full statistical analysis plan, including definition of the non-inferiority margin and sensitivity analyses, is being developed in collaboration with a biostatistician.

6. Recruitment pathway

Identification and recruitment of participants

The participants can be identified through the following pathways:

- 1. During hospital admission
- 2. During visits to the outpatient clinic
- 3. During scheduled ultrasound visits

Potential participants will be identified from antenatal visits based on the inclusion criteria. There are 2 pathways for screening and providing information; primary and secondary screening.

Primary screening: When a woman meets the inclusion criteria, the healthcare professional involved in her care will ask for verbal consent to add her to a dedicated list in the electronic patient record (*BEWISE list*) to be contacted by a research asisstant for further verbal and written information about the study. This information will be given either by telephone or video consultation (for instance in case of a long travel distance to the hospital and prescribed bed rest) or in person.

If the woman consents for participattion, she will sign an electronic consent form.

Secondary screening: The research assistants will be located at the four university hospitals. We expect that most of the eligible participants will be referred to and therefore included in the study at these hospitals. To ensure completeness of recruitment and to validate the implementation of the new recommendations, the research assistant will review relevant outpatient booking lists at their own department at the university hospital. The information extracted from the patient files will include gestational age, cervical length, and plurality. Approximately 3,000 records will be screened during the study period from February 2026 to January 2029, and only information from this same time period will be viewed. This process aims to identify women who may have been overlooked during their antenatal visits and therefore were not added to the BEWISE list. These women will be identified based on the inclusion criteria for the study. We expect the number of women identified through this pathway to be small. We will not screen the outpatient booking lists at the regional hospitals as we expect the number of eligible patients there to be very small. If eligible women are identified through this secondary screening, the research assistant will make a note of it in the patient file. The next time the participant visits the department, the healthcare professional will read the note and be able to ask for verbal consent, following the same pathway as descirbed in the primary screening.

We expect the majority of participants to be informed and recruited through the primary screening. Regardless of how the women are identified, the information process is similar for all participants and consists of both written and verbal information.

No public advertisement or social media recruitment will be used.

Initial contact with participants

Initial contact will be made by a member of the clinical team involved in the patient's care, either at the outpatient visit where a short cervix is detected or during admission. After this she will receive written information on the trial and be invited to receive further information from the research assistant, have the SENS activity tracker applied and have the first blood test drawn (if eligible).

Procedure for obtaining informed consent

The consent form is digital, and all signatures are written on a smart phone, a tablet, or a computer using Research Electronic Data Capture (REDCap) which has dedicated functionalities for written consent that are in accordance with the law of data protection.

All participants will be informed of their right to bring a support person to the information session.

Participants will be given appropriate time for consideration (an appropriate amount of time is agreed upon individually allowing for a minimum of 24 hours if needed).

Written informed consent will be obtained prior to any study-related procedures. In the consent form, participants may choose to consent to one or more of the following components:

1. Access to their medical records and collection of data for the study from medical records and electronic questionnaire
2. Wearing the SENS activity tracker and collection of data from the device
3. Blood sampling (if applicable)
4. DXA scan (if applicable).

Participants may withdraw their full or partly consent at any time without providing a reason and without any consequences for their ongoing care.

The consent gives the principal investigator, the sponsor and the sponsor's representatives, as well as any relevant regulatory authorities, direct access to obtain information from the patient's medical records, including electronic records, in order to review information about the trial subject's health conditions that is necessary for the conduct of the research project and for control purposes, including internal audits, quality control, and monitoring, which they are obliged to carry out.

7. Risks, side effects, and disadvantages

Risks

Blood samples: Taking a blood sample is a safe routine procedure. The risk of infection is very low when standard hygiene procedures are followed. If a patient has symptoms of infection she may see her general practitioner for assessment, advise and treatment.

DXA scans: Each DXA scan involves exposure to a very low dose of ionizing radiation. The effective dose is typically in the range of 0.001–0.01 mSv per scan, which is less than a day of natural background radiation in Denmark (average background radiation ≈ 3 mSv per year). This dose is far below the threshold of 0.1 mSv and therefore places the project in Category I according to the Danish radiation guidelines [31].

At this dose level, the risk of stochastic damage is negligible (on the order of 1 in 1,000,000 or less). Consequently, the potential radiation risk to participants can be regarded as insignificant.

SENS: The materials in the activity tracker and the band-aid securing its place may cause skin irritations or allergic skin reactions.

Possible side effects

Blood samples: Mild discomfort, bruising, or slight bleeding at the puncture site may occur. Some participants may feel dizzy or faint, standard observation measures will be followed if this occurs.
DXA scans: A DXA scan requires lying still on an examination couch for a few minutes, which might be uncomfortable for some individuals (e.g., those with back pain or claustrophobia), but there is no physical discomfort from the scan itself.
SENS: Wearing the SENS activity tracker may lead to a feeling of being monitored, which could cause stress or anxiety in some participants.

Disadvantages

Participants may experience some inconvenience due to the time commitment required for the study. This includes potential additional visits to the hospital related to DXA scans, blood sampling, and use of the activity tracker.

8. Collection of new biological material

We will collect blood samples on approximately 140 participants at baseline, after 4 weeks and after 8 weeks. Each blood sample will consist of 3-6 ml of blood.

The purpose is to measure the bone turnover markers procollagen type I N-propeptide and carboxy-terminal telopeptide of type I collagen.

The blood samples will be stored at the laboratory in a research biobank until the end of the study, at which point they will all be analysed. Afterwards, the samples will be destroyed immediately.

The blood samples will be stored between 6-18 months, so we are able to analyse them all at once, minimizing the risk of instrumentation bias.

9. Variables

Collected variables will be used for baseline descriptive statistics and for outcome analysis.

Data variables

Maternal characteristics at time of inclusion

Self-reported information at time of consent:

- Employment status
- Education level
- Ethnicity
- Marital status

Collected information from the in-hospital electronic medical records:

- Maternal age
- Body mass index (BMI)
- Parity
- Congenital uterine malformation
- Previous conization
- Date at recruitment
- Previous pregnancies and outcomes of the pregnancies
- Ultrasound determined due date
- Cerclage treatment
- Danish region

Obstetric data during pregnancy

Collected information from the in-hospital electronic medical records from time of inclusion until birth.

- Treatment with: vaginal progesterone, tocolysis, magnesium sulphate and/or lung maturation
- Preterm prelabour rupture of membranes
- Shortest sonographic cervical length
- Number of contacts to obstetric department
- Total number of admission days in the obstetric department before onset of labour/caesarean section
- Level of recommended activity restriction at time of inclusion
- Pessary
- Cerclage
- Gestational diabetes mellitus
- Preeclampsia
- Gestational hypertension
- Eclampsia

Data from the SENS activity tracker

- Step count
- Time in a supine position

Obstetric data during birth

Collected information from the in-hospital electronic medical records after birth

- Date and time at onset of birth (active labour)
- Date and time at birth or loss
- Onset of birth (spontaneous, induction, CS)
- Mode of birth
- Fetal presentation
- Oxytocin-infusion during birth
- Epidural anaesthesia during birth
- Placental abruption
- Post partum haemorrhage

- Administration of iv antibiotics
- Retained placenta (transferred to operating theatre)
- Fetal asphyxia
- Degree of birth tear
- Smoking status
-

Neonatal data

Collected information from the child's in-hospital electronic medical records

- Date and time of neonatal death (within the first 28 of life)
- Birth weight
- Date at time of discharge from the hospital
- Intraventricular haemorrhage
- Periventricular leukomalacia
- Retinopathy of prematurity
- Surgery due to necrotizing enterocolitis or spontaneous intestinal perforation
- Mechanical ventilation or non-invasive ventilation (NIV)
- Administration of iv antibiotics
- Date at initiation and discontinuation of iv antibiotics
- Apgar score at 5 minutes
- Umbilical cord pH
- Blood sugar level

The data are used to identify differences in demographic and pregnancy-related factors between the groups that may explain any differences in pregnancy outcomes. In addition, data on pregnancy outcomes are collected for the main purpose of the project, namely to compare the two treatments in terms of pregnancy prognosis and the participant's health.

10. Processing of personal data in the project

Data will be handled according to national laws on data protection (in Denmark including the General Data Protection Regulation and the Data Protection Act) and will be registered at www.ClinicalTrials.gov. In Denmark, the project will also be registered with the Central Denmark Region's internal list of research projects. Data will be used for the purpose outlined in this trial protocol.

11. Economy

The trial is investigator-initiated. The Independent Research Fund Denmark has funded the trial with approximately 4,2 million DKK.

The funding is administered at the Department of Gynaecology & Obstetrics, Aarhus University Hospital, Denmark and can be used for salary for named collaborators, data handling, and additional operational

expenses according to the funding terms. Private and public funds will be sought for additional costs. The funding agencies will have no role in any aspects of conducting and reporting of the trial.

The Health Research Foundation of Central Denmark Region has funded 100.000 DKK for salary for a research assistant during the preparation of the trial. This funding was administered by the Department of Gynaecology & Obstetrics, Viborg Regional Hospital, Denmark.

12. Dissemination policy

The study will be registered at www.clinicaltrials.gov.

Positive, inconclusive as well as negative results from the trial will be published in peer reviewed international scientific journals. Results will furthermore be presented at national and international conferences and shared via public and social media platforms.

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