The Effect of Routine Activity on the Risk for Preterm Delivery in Women with a Short Cervix: A Randomized Controlled Trial

Principal Investigator: Dr. Eliel Kedar Sade

Email: Elielbob@gmail.com

Phone: +972-52-6008068

Co-Investigator: Dr. Julia Barda

Institution: Department of Obstetrics and Gynecology, Edith Wolfson Medical Center

62 HaLochamim St., Holon, Israel

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Background:

Preterm birth is defined as delivery occurring before the completion of 37 weeks of gestation (1). The incidence of preterm birth is estimated to be approximately 10% of all deliveries (2) and represents a significant cause of perinatal morbidity and mortality (3-6). Pregnant women with a shortened cervix, as determined by transvaginal ultrasound, are at an increased risk of preterm delivery (7-8). Traditionally, bed rest has been recommended for women at risk of preterm birth. Studies suggest that approximately 18% of pregnancies in the United States receive a recommendation for bed rest at some point during pregnancy (9). The rationale for bed rest has been based on the assumption that physical exertion and strenuous activity could be associated with preterm labor and that rest may reduce uterine activity (9-11). Despite the widespread use of this recommendation in obstetrics, very few prospective randomized trials have been conducted to examine its effectiveness. A recent Cochrane review on bed rest for preventing preterm birth identified only one study, which included 1,266 women (12). The study found no significant difference in preterm birth rates before 37 weeks between women assigned to full bed rest and those who did not receive any specific intervention (7.9% vs. 8.5%). Additionally, there was no evidence that bed rest reduced preterm birth rates among women with a short cervix (13). Only one study has quantitatively assessed the relationship between physical activity and preterm birth risk in women with a short cervix (14). The study evaluated 49 women with a short cervix who were instructed to wear a step-counting device for at least one week. Participants were not given specific instructions on activity limitations. The study found no benefit to reducing physical activity levels for preventing preterm birth. In fact, women with lower step counts had a higher rate of preterm birth.

Rationale for the Study: The study aims to examine the effect of routine activity in pregnant women with a short cervix on gestational age at delivery.

Study Objective: To assess the impact of routine activity on the risk of preterm birth in pregnant women between 24 and 34 weeks of gestation with a sonographically diagnosed short cervix.

Primary Outcome:

- Gestational age at delivery.

Secondary Outcomes:

- Incidence of preterm contractions.
- Incidence of premature rupture of membranes (PPROM).
- Mode of delivery (cesarean section, instrumental delivery, spontaneous vaginal delivery).

Methods

Study Design This is a prospective, randomized, controlled trial comparing two groups.

Study Procedure

1. A computer-generated 1:1 randomization scheme will allocate participants to either the intervention or control group.
2. Women attending hospitalization or high-risk pregnancy clinics at Wolfson Medical Center between 24+0 and 34+6 weeks of gestation, diagnosed with a short cervix (<25 mm) via transvaginal ultrasound, will be approached by a physician and informed about the study.
3. Upon obtaining informed consent, participants will be enrolled in the study. Upon discharge, they will receive a smart band to monitor step counts. The monitoring period will last for two weeks.
4. Participant allocation will be conducted using the pre-generated randomization scheme and sealed opaque envelopes managed by an external research nurse.
5. All participants, regardless of study group assignment, will be granted medical leave from work.
6. Control Group (Routine Activity): Participants in this group will be instructed to continue their normal, non-strenuous routine activities without a recommendation for maximal rest.
7. Intervention Group (Maximal Rest): Participants in this group will be instructed to follow maximal rest guidelines, avoiding strenuous activities such as prolonged standing, carrying heavy items, or lifting children.
8. Participants will continue to receive regular follow-up in hospitalization or high-risk pregnancy clinics as per standard departmental protocols.
9. Each participant's smart band data will be linked to a dedicated email address, ensuring step count data remains blinded to researchers until study completion.
10. Step-count monitoring will cease immediately after delivery.

Eligibility Criteria

<u>Inclusion Criteria:</u>

- Pregnant women between 24+0 and 34+6 weeks of gestation.
- Singleton pregnancies.
- Short cervix (<25 mm) confirmed via transvaginal ultrasound.
- No medical contraindication to mobility.

<u>Exclusion Criteria:</u>

- Declining study participation.
- Medical recommendation to restrict mobility (e.g., symphysiolysis, high fall risk).
- Significant maternal comorbidities.
- Fetal distress.
- Vaginal bleeding.
- PPROM.
- Medical indication for immediate preterm delivery.
- Twin or higher-order multiple pregnancies.

Withdrawal Criteria:

- Medical indication requiring preterm delivery or urgent intervention (e.g., fetal distress, maternal complications).
- Medical condition requiring strict activity limitation, contrary to group allocation.
- Participant non-compliance with study protocol, including smart band usage.

Study Variables

Primary and secondary endpoints will be assessed based on: Step count. Number of follow-up days. Gestational age at delivery. Obstetric outcomes. Demographic characteristics (BMI, age, parity, history of preterm birth). Cervical length at diagnosis.

Data Collection

Medical data, including height, weight, age, and delivery details, will be collected from the hospital's electronic medical system (Cameleon).

Step count data will be retrieved from the dedicated email address linked to each participant's smart band at the end of the monitoring period.

Statistical Methods

Sample Size: 100 participants.

Data Analysis: Data will be analyzed using SPSS. Continuous variables will be presented as median and interquartile range (IQR). Comparisons will be made using t-tests or Mann-Whitney tests for continuous variables. Categorical variables will be compared using chi-square or Fisher's exact tests. Correlations will be

analyzed using Pearson or Spearman tests. Logistic regression will be conducted to identify factors significantly associated with preterm birth.

Study Timeline Duration: Two years.

Participant follow-up: Begins at enrollment and continues until delivery.

Step count monitoring: Two-week period during pregnancy.

Ethical Considerations

The study is funded by the Department of Obstetrics and Gynecology, Edith Wolfson Medical Center. Participants may withdraw at any time without affecting their medical care.

The study question is specific to pregnant women, and the results may help optimize management strategies for this population.

Data Privacy

Each participant will be assigned a random identification number. Personal identifiers (name, ID number, address) will be securely stored on the principal investigator's locked computer, accessible only to authorized personnel.

Informed Consent

All participants will receive both verbal and written explanations of the study from the research team before signing the informed consent form.

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