

TITLE

Effectiveness of membrane sweeping on successful initiation of labor and subsequent vaginal birth in patients with previous one cesarean section.

NCT No. 06103071

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Study Protocol

This Randomized controlled trial was conducted at HIT Hospital, Taxila, in collaboration with POF Hospital, Wah Cantt, from 15th Jan 2023 to 15th July 2024. The determined sample size overall amounts to 384 patients. The sample size is determined using the WHO calculator by calculating a 95% confidence interval, 80% statistical power, and a % expected success rate of 50% using membrane sweeping.

Women at gestational age of 37 weeks to 40 weeks who were willing for vaginal birth and who had a history of one prior caesarean procedure for non-recurrent reasons were included in the research. Females with multiple gestation or non-cephalic presentations, previous uterine rupture, major degree placenta previa, medical disorders like pregnancy-induced hypertension, gestational or chronic diabetes or having bad obstetrics history were excluded from the study.

The trial was registered in the clinical trial registry after obtaining approval from the institutional review board of HITEC-IMS and Wah Medical College. Patients with previous cesarean sections attending the gynaecology department at HIT Hospital and POF Hospital who fulfilled the inclusion criteria were enrolled, and informed consent was obtained. Two groups were made by using the lottery method. Group A is an interventional group in which membrane sweeping was done. Group B is a control group that includes women without membrane sweeping. The lottery method was used to randomly assign patients to either group A or B so every patient has an equal chance of getting selected for intervention. For membrane sweeping, the doctor inserts one or two fingers into the cervix and continuously sweeps the inferior pole of the membranes from the lower uterine segment. Weekly membrane sweeping was done starting at 37 weeks till the initiation of labour or 40 weeks of gestation, whichever happened first. Patients in which spontaneous labour did not start till 40 weeks were planned for elective cesarean section in the next operation theatre list according to the protocol of the department. Numerical data, including age and parity, were recorded. The primary outcome measures the number of patients who had onset of labour till 40 weeks. Secondary outcome measures of successful vaginal delivery and fetal outcome, i.e. admission to NICU, were recorded.

Data Analysis Plan

All data was entered and analyzed using computer software for statistical package for the social sciences (SPSS) version 28. Mode of delivery and admission in NICU were compared in both groups using the chi-square test. P value <0.05 was considered as significant.

Consent Form

This study is conducted to increase the onset of labor in patients with previous one cesarean section in order to reduce cesarean section rate. Your confidentiality and privacy will be ensured. In this study we have divided patients in two groups. Group A includes women in which membrane sweeping will be done and group B includes women in which no membrane sweeping will be done. Group will be allocated on random basis and you may be included in any group.

If you go in labor then success of vaginal birth is 72% to 75%. Your chances of vaginal birth are increased in future pregnancies with shorter hospital stay. In case of vaginal birth you will be prevented from risks of operation and more likely to have immediate skin to skin contact with baby and able to breastfeed successfully.

Along with above mentioned benefits there is also a risk of having emergency caesarean section during labor and its incidence is 25 out of 100 women. 1 in 200 women is at risk of having scar dehiscence (rupture). This risk increases by 2 to 3 times if your labor is induced by pharmacological methods. Being a non-pharmacological method, sweeping of membranes causes no significant harm to mother or baby.

I have read the consent and understood its content and I therefore, give my willingness for participation in the study.

Signature
