RESEARCH STUDY INFORMATION

This randomized clinical trial, carried out in Helsinki University Hospital (the maternity departments Naistenklinikka and Espoo Hospital) includes 650 women whose labor is induced for prolonged pre-labor rupture of membranes. The study compares two induction methods already in use: Balloon catheter and misoprostol tablets. In addition, we will investigate the effectiveness and need of antibiotics in the balloon group.

When the uterine cervix is immature (long, closed, rigid), induction is initiated by ripening the cervix. At the choice of the clinician and mother, the ripening takes place either **mechanically with a balloon catheter** (releases cervical prostaglandin hormones) or **medically with oral misoprostol tablets** (artificial prostaglandin hormone). Both ripening methods are safe and effective and have been used for a long time in various induction **indications** in our delivery units.

The aim of the study is to collect additional information on these induction methods in women with ruptured membranes, and we will randomize the women participating in the study to balloon catheter or misoprostol group (Part A of the study).

When the labour is induced with a balloon after the rupture of membranes, treatment practice at Helsinki University Hospital is to routinely administer 1-2 doses of intravenous penicillin antibiotic to the woman giving birth for the duration of the balloon being in place. This is not based on scientific evidence. **The second objective of the study is to collect information on the use of antibiotics, their efficacy and necessity in connection with balloon induction after the membranes have ruptured. In this part, the women giving birth in the balloon group are randomised to "antibiotic" or "no antibiotic" groups (Part B of the study).**

You can participate in the study if:

- Your membranes have ruptured but labor contractions have not started within 24 hours and there are no contraindications to vaginal delivery
- You are a first-time mother or have given birth before
- Your pregnancy is full-term (≥37 weeks of pregnancy) and singleton
- Your uterine cervix is unripe
- GBS (Group B streptococcal bacteria) is not detected in the vagina
- The baby is head down and has been assessed as normal weight
- You have not undergone a caesarean section previously

Participating in the study is voluntary and participation does not have an effect on the treatment of labour, but it is implemented in accordance with normal treatment practices.

We are happy to answer any questions you may have regarding the study

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HUS Helsingin yliopistollinen sairaala