

The safety of out-patient compared with in-patient treatment in women with preterm prelabor rupture of the membranes (PPROM) prior to 34 weeks of gestation

Submission date 07/05/2018	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 11/05/2018	Overall study status Stopped	☐ Statistical analysis plan
		☐ Results
Last Edited 04/01/2023	Condition category Pregnancy and Childbirth	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Premature birth can begin with contractions or with the premature breaking of the mother's waters (preterm prelabor rupture of the membranes, PPRM). About three or four of every ten deliveries start with PPRM. The most common reason for that is inflammation in the uterus (womb) or amniotic membranes (the double sac containing the baby and the amniotic fluid). PPRM does not always lead to immediate labor, so the pregnancy can go on for several weeks after PPRM. After PPRM there is an increased risk for chorioamnionitis (infection of the double membranes around the baby). Pregnant women who have had PPRM need to be monitored closely for signs of this infection. The current standard in Helsinki University Hospital is to follow up pregnancies after PPRM in the antenatal (pre-birth) ward. There is not enough research published on the need for hospital admission after PPRM in the absence of chorioamnionitis. The aim of this study is to examine if out-patient treatment after PPRM is as safe as in-patient treatment.

Who can participate?

Women with PPRM at 20-34 weeks of pregnancy with singleton pregnancy and no signs of infection or fetal distress.

What does the study involve?

Women with PPRM between 20+0 and 33+6 weeks of pregnancy coming to hospital are informed about the study. All women receive intravenous antibiotics for 3 consecutive days. Amniocentesis (taking some fluid from around the baby) is performed to rule out subclinical chorioamnionitis. After receiving more information and having given her consent, if a woman is eligible for a study, she will be randomized to out-patient or in-patient treatment until the birth of her baby. In case of infection, the patient will be treated as the medical situation requires. The mother will fill in a questionnaire when she first joins the study and at 34 weeks of pregnancy after the birth if it is before 34 weeks.

What are the possible benefits and risks of participating?

There are no specific risks for those taking part in this study. Women who are randomized to the out-patient group can stay at home rather than stay in hospital several weeks after PPRM as in the usual treatment.

Where is the study run from?

Helsinki University Hospital

When is the study starting and how long is it expected to run for?

December 2017 to December 2020

Who is funding the study?

There is no additional funding needed to run the study

Who is the main contact?

Dr Tarja Myntti, tarja.myntti@hus.fi

Contact information

Type(s)

Scientific

Contact name

Dr Tarja Myntti

Contact details

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Additional identifiers

Protocol serial number

HUS/456/2018

Study information

Scientific Title

The safety of outpatient compared to inpatient treatment in women with PPRM prior to 34 weeks of gestation: a randomized controlled trial

Acronym

SAIKO

Study objectives

The safety of outpatient treatment in women with PPROM prior to 34 weeks of gestation is equivalent to the safety of inpatient treatment

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hospital district of Helsinki and Uusimaa Ethics committee for Women's and Children's Health and Psychiatry, 07/03/2018, HUS/456/2018

Primary study design

Interventional

Study design

Randomised controlled single-center trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Preterm prelabor rupture of the membranes (PPROM), homecare vs hospital care

Interventions

Women with PPROM before 34+0 weeks of gestation are recruited to this study when they come to hospital. Everyone receives intravenous antibiotics for 3 consecutive days.

Amniocentesis is performed to rule out intra-amniotic infection.

Randomization is performed by picking closed, opaque envelope from the box. The envelope includes a paper with a text "home treatment" or "hospital treatment".

Out-patient treatment:

Women are sent home, and they will have check-ups at hospital twice a week during the first 2 weeks, and after that once a week. At every visit cardiotocography (CTG), C-reactive protein (CRP) and leukocyte values are checked, and once a week a doctor will examine the cervix and perform an abdominal ultrasound examination. At home they measure their temperature and contact the hospital if they have a fever, the baby is not moving, they have odorous discharge from the cervix, or they start to have regular contractions.

In-patient treatment:

Daily CTG, daily point-of-care CRP testing. Ultrasound examination, laboratory leukocyte count and hemoglobin once a week. Individual plan for delivery at gestational age 34+0, or before, if any signs or symptoms of clinical chorioamnionitis. In-patients can move around the ward freely if the length of cervical canal is >10 mm.

Intervention Type

Other

Primary outcome(s)

Infectious events in mothers and in neonates during pregnancy and for 2 weeks after birth.

Key secondary outcome(s)

1. Length of the pregnancy after PPROM
2. Any events in the pregnancy after randomization

3. Apgar scores at 1 min and 5 min after birth and pH values of the neonates
4. Venous and arterial blood pH value for the neonate is measured using blood taken from the umbilical cord immediately after delivery
4. Satisfaction of the mothers. The women will fill the first part of the satisfaction questionnaire immediately after randomization, and the second part at 34+0 weeks of gestation, when an individual plan for the delivery is made, or before that if the delivery starts spontaneously.

Completion date

30/12/2020

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. PPRM at gestational weeks 20+0 to 33+6
2. No clinical signs of infection
3. No subclinical infection in amniocentesis
4. Willing to participate
5. Singleton pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Severe Intrauterine growth restriction (IUGR) or redistribution in fetal blood flow
2. Symptomatic pre-eclampsia, or pre-eclampsia with blood pressure medication, proteinuria, or abnormal laboratory values
3. Clinical infection in vagina or uterus, or HIV infection
4. Inadequate language skills to understand the written medical consent or handout of the study
5. Diabetes Type 1

Date of first enrolment

10/04/2018

Date of final enrolment

28/02/2020

Locations

Countries of recruitment

Finland

Study participating centre

Helsinki University Hospital and University of Helsinki

Haartmaninkatu 2

00290 Helsinki

Helsinki

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Sponsor information

Organisation

Helsinki University Hospital

ROR

<https://ror.org/02e8hzf44>

Funder(s)

Funder type

Not defined

Funder Name

Helsinki University Hospital

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date .

IPD sharing plan summary

Stored in repository