

# 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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/05/2018	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/01/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Study design**

Randomised controlled single-center trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Finnish language information sheet available on request

**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 measure**

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

### **Secondary outcome measures**

1. Length of the pregnancy after PPRM
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.

### **Overall study start date**

15/12/2017

### **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

### **Age group**

Adult

### **Sex**

Female

### **Target number of participants**

126 (63 in each group)

**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

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**Sponsor information****Organisation**

Helsinki University Hospital

**Sponsor details**

Haartmaninkatu 2

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**Sponsor type**

Hospital/treatment centre

**ROR**

## Funder(s)

### Funder type

Not defined

### Funder Name

Helsinki University Hospital

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

### Intention to publish date

30/12/2020

### 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