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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

Registration date
11/05/2018

Overall study status
Stopped

Last Edited
04/01/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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, PPROM). About three or four of every ten deliveries start with PPROM. 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). PPROM does not always lead to immediate labor, so the pregnancy can go on for several weeks after PPROM. After PPROM there is an increased risk for chorioamnionitis (infection of the double membranes around the baby). Pregnant women who have had PPROM need to be monitored closely for signs of this infection. The current standard in Helsinki University Hospital is to follow up pregnancies after PPROM in the antenatal (pre-birth) ward. There is not enough research published on the need for hospital admission after PPROM in the absence of chorioamnionitis. The aim of this study is to examine if out-patient treatment after PPROM is as safe as in-patient treatment.

Who can participate?
Women with PPROM at 20-34 weeks of pregnancy with singleton pregnancy and no signs of infection or fetal distress.

What does the study involve?
Women with PPROM 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 oh 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 PPROM 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?
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Contact information

Type(s)
Scientific

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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 PPROM 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 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.

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. PPROM 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
00290 Helsinki
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Sponsor information

Organisation
Helsinki University Hospital

Sponsor details
Haartmaninkatu 2
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Sponsor type
Hospital/treatment centre

ROR

https://ror.org/02e8hzf44

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