ISRCTN65694106 https://doi.org/10.1186/ISRCTN65694106

The effect of rectal progesterone on labor, and the prevention of preterm delivery, as well as minimizing the maternal and prenatal complications due to Preterm Premature Rupture Of Membrane (PPROM)

Submission date
25/05/2014

Recruitment status
No longer recruiting

Registration date
18/07/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Preterm premature rupture of the membranes (PPROM) is a problem directly linked to prematurity that can cause severe newborn complications and even death. Research has shown that weekly injections of 17-alpha-hydroxyprogesterone (17P) or daily progesterone application in the vagina decreases the number of preterm deliveries, notably in those with a history of a prior preterm delivery and those with a shortened cervix discovered by ultrasound examination. Infection stimulates the production of pro-inflammatory cytokines that are commonly associated with preterm birth and PPROM. Studies have suggested that 17P can maintain pregnancy and prevent PPROM. Furthermore, no studies have yet been conducted to see the effect of vaginal or rectal progesterone on latency period (defined as the period from the onset of PROM until onset of labour). The safety of using vaginal progesterone in PPROM is questionable; thus, the vaginal route will be replaced by the rectal route. Our primary aim is to study the effect of rectal progesterone on the latency period of PPROM.

Who can participate?
Women aged 18-45 years old who are between 24 and 33 weeks pregnant, with a confirmed diagnosis of PPROM.

What does the study involve?
The patients will be randomly allocated to receive either rectal progesterone or a placebo (dummy) suppository on a daily basis. Daily rectal progesterone or placebo suppository continue until 35 weeks or delivery, whichever comes first. Patients, their families, research personnel, and physicians/nurses will not be aware of the study group assignment. Women will be given a 7-day course of antibiotics and will receive full courses of steroids for foetal lung maturation. After their stay in the labour and delivery area, patients will be transferred to the high-risk floor. All patients will have vaginal swab testing, routine foetal testing and frequent assessments for

infection. All patients will stop therapy at 35 weeks. There will be no additional visits or costs due to the study itself.

What are the possible benefits and risks of participating?
The study drug has no side effects except for the minor possibility of an allergic reaction in rare cases. Refusing to participate in the study will not affect the patients medical care. Patients will have the right to withdraw from the study at any point.

Where is the study run from?
The study will be carried out at the following four centers in Jeddah, Saudi Arabia:

1. King Abdulaziz University Hospital (KAU Hospital)
2. Dr.Soliman Fakeeh Hospital
3. King Faisal specialist hospital and Research Center (KFSH&RC)
4. International Medical Center

When is study starting and how long is it expected to run for?
Recruitment starts in July 2014 and will continue over a period of 7 months.

Who is funding the study?
Institute of Scientific Research and Revival of Islamic Heritage, Umm Al-Qura University, Saudi Arabia.

Who is the main contact?
Dr Fadawh Tahir, Fadwaht@gmail.com
Prof. Muhammad Irfanullah Siddiqui, irfan7255@yahoo.com, irfan7255@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Fadwah Tahir

Contact details
Jeddah- Al Nozlah
Jeddah
Saudi Arabia
21478

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
30

Study information

Scientific Title
The effect of rectal progesterone on the latency period as well as maternal and prenatal outcome in PPROM between 24-33+6 Weeks

Acronym
PPROM

Study objectives
It is hypothesized that rectal progesterone can prevent preterm labor, which in turn reduces fetal mortality and morbidity. The null hypothesis is that there will be no difference between the placebo group and the rectal progesterone group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Faculty of Medicine, Umm Al-Qura University, 17/02/2014, ref: 14/BME /0030

Study design
Multi-centre triple-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Preterm premature rupture of membrane (PPROM)

Interventions
Rectal progesterone (Cyclogest) and placebo

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To determine the effect of rectal progesterone on the Latency Period in PPROM. The outcomes will be measured using three forms: recruitment form, follow-up form, and research end form. These forms where designed by the authors using focused group discussion. These forms will be completed by the treating physicians. The recruitment and the research end forms will be completed only once, when the patient agrees to participate in the study and when the patient is discharged from our care, respectively. The follow-up form will be filled twice weekly.

Secondary outcome measures
To find out the effect of rectal progesterone on maternal outcomes of:
1. Hospitalization
2. ICU admission
3. Chorioamnionitis
4. Post-partum haemorrhage
5. Post-partum pyrexia
6. Endometritis
7. Maternal death

Prenatal outcome of:
1. Birth weight
2. Apgar score
3. Neonatal morbidity
4. Neonatal intensive care unit (NICU) stay
5. Intrauterine fetal death (IUFD)
6. Neonatal death in PPROM

Overall study start date
01/06/2013

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. 18-45 years old
2. Singleton live fetus
3. 24 to 33 weeks
4. Confirmed PPROM

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
216

Key exclusion criteria
All fetal & maternal conditions that could affect fetal and maternal outcomes

Maternal:
1. Maternal fever
2. Antepartum haemorrhage
3. Chorioamnionitis
4. Preterm labour (PTL)
5. Pre-existing diabetes
6. Preeclampsia
7. Cervical cerclage
8. Severe medical diseases
9. Allergy to progestin or placebo
10. Medical condition that might adversely interact with progesterone
11. Medical condition treated with systemic steroid
12. PPROM >48 hours prior presentation
13. Unsure gestational age

Fetal:
1. Fetal chromosomal abnormality
2. Fetal anomaly
3. Non reassuring surveillance (BPP < 4 / 10)
4. IUGR

Date of first enrolment
01/03/2016

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Jeddah- Al Nozlah
Jeddah

Saudi Arabia
21478

Sponsor information

Organisation
Umm Al-Qura University

Sponsor details
Institute of Scientific Research and Revival of Islamic Heritage
Makkah, third ring road
Makkah
Saudi Arabia
715

Sponsor type
University/education

Website
http://uqu.edu.sa/page/en/242

ROR
https://ror.org/01xjqrm90

Funder(s)

Funder type
University/education

Funder Name
Institute of Scientific Research and Revival of Islamic Heritage, Umm Al-Qura University (Saudi Arabia)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/11/2015	10/05/2021	Yes	No