

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Tocolysis vaginal progesterone ether as preservatives in preventing preterm delivery

Protocol summary

Summary

The aim of this study is evaluation of effect of vaginal progesterone as maintenance tocolytic in prevention of preterm labor. Inclusion criteria: single tone pregnancy with 24-34 gestational age with premature delivery confirmed and intact fetal membranes. Exclusion criteria: rupture of membranes, fetal anomaly and dysteress during the study and medical disease of peregnant women. Material and methods: 200 pregnant women with inclusion criteria admitted in the Kosar hospital with a diagnosis of preterm labor. Randomaly divided into two groups with 100 peoples. Control group treated with magnesium sulfate intravenously with initial dose of 4-6 gr and 2-4 gr per hours maintenance dose up to 24 hours and a corticosteroid, 2 doses of 12 mg betamethasone, with a 24 hours interval. In the treatment group in addition of the above-mentioned drugs, 200 mg of progesterone vaginally at the start of treatment and then adminstrated every 12 hours until disappearance of the uterine contractions. In the treatment group a 200 mg vaginal progesteron suppository daily given until the end of 34 weeks or delivery. Study outcomes is maternal-neonatal outcomes (the duration of time between start of treatment and stop contraction, latancy phase, apgar scores and birth weight, newborn complications until the end of 28 days, duration of admission in nicu, need to use ventilator and neonatal death that compared between control and treatment groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112331046N1**

Registration date: **2017-05-29, 1396/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-29, 1396/03/08

Registrant information

Name

Fahimeh Takallo

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Tocolysis vaginal progesterone ether as preservatives in preventing preterm delivery

Public title

The effect of progesterone in the prevention of preterm delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancies between 24-34 weeks gestational age; premature delivery confirmation by: regular uterine contractions (with a length of more the 30 second and more than 3 times per 10 minutes) with dilatation of the cervix 0-2 centimetres in noliars and 0-3 centimetre in moltipars; intact fetal membranes. exclusion criteria: rupture of the membranes during treatment; fetal anomaly; any evidence of fetal distress (chorioamnionitis, Preeclampsia, placental abruption, intrauterine growth restriction); sensitivity to progesterone (dizziness, headache, depression, high blood sugar during usage); history of medical illness in the mother (high blood pressure, cancer, epilepsy, chronic thromboembolic disease, liver disease); patients with asthma treated with oral beta-adrenergic.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

NO

Secondary trial Id

NO

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blvd, Qazvin

City

Qazvin

Postal code

Approval date

2015-11-04, 1394/08/13

Ethics committee reference number

IR.QUMS.REC.1394.200

Health conditions studied

1

Description of health condition studied

Preterm labour without delivery

ICD-10 code

O60.0

ICD-10 code description

Preterm labour without delivery

Primary outcomes

1

Description

Delay of delivery

Timepoint

post partum

Method of measurement

documented data

Secondary outcomes

1

Description

Neonatal distress

Timepoint

after delivery

Method of measurement

Documented data

2

Description

Birth weight

Timepoint

After delivery

Method of measurement

Documented data

3

Description

Apgar at birth

Timepoint

After delivery in 1 and 5 minutes

Method of measurement

Documented data

4

Description

Gestational age at birth

Timepoint

after delivery
Method of measurement
documented data

5

Description
Perinatal Mortality

Timepoint
after delivery

Method of measurement
documented data

6

Description
Fetal death

Timepoint
after delivery

Method of measurement
documented data

7

Description
NICU admission

Timepoint
after delivery

Method of measurement
documented data

Intervention groups

1

Description
Giving 200mg vaginal progesterone in case group after confirmed preterm labor and treat with sulfate manazum and corticosteroid. If the pain isn't off after 12 hours it is repeated then after of control pain it is giving daily until 34 weeks or delivery.

Category
Treatment - Drugs

2

Description
In control group after confirmed preterm labor none drug in addition of sulfate manazum and corticosteroid is given.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Dr Fahimeh Takallo

Street address
Kowsar Hospital, Taleghani St, Qazvin, Iran
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research of Qazvin University of Medical Sciences
Full name of responsible person
Dr Amir Peymani
Street address
Bahonar Blvd , Qazvin , Iran
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Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research of Qazvin University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kowsar Hospital
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Person responsible for scientific inquiries

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty

Person responsible for updating data

Contact

Name of organization / entity

Kowsar Hospital

Full name of responsible person

Dr Fahimeh Takallo