Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison effects of Progesterone by vaginal suppository and betamimetics to reduce preterm birth in women at risk

Protocol summary

Summary

This is a randomized clinical trial to evaluate the effect of administering progesterone to reduce premature labor in women at high risk. This study was done on 56 pregnant women between 26 to 34 weeks, who were at the risk of premature labor that visited by doctor or clinic Hospital. At the beginning of the study 6 patients were excluded from the study due to fetal abnormalities, preeclampsia, and sensitivity to progesterone. Then patients were Inclusion criteria, randomly divided into two 25 person groups (experiment and control group). Inclusion criteria are including cervical insufficiency, history of premature labor and uterine abnormalities. In the first visit their vaginal discharge were considered about trichomona, gardenella, B streptococus and gonorrhea, and treated. In the experiment group progesterone supp (200mg) was prescribed every 2days until the end of 34 week of pregnancy. In the control group tab salbutamole (2mg TID) was prescribed until the end of 34 week of pregnancy. The patients continued treatment outpatient at home and referred for following up pregnancy and contractions (every 2 weeks).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108286808N2**
Registration date: **2012-02-04, 1390/11/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-04, 1390/11/15

Registrant information

Name

Maryam Tolyat

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 9056

Email address

tolyatm@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Science

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2010-02-04, 1388/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of Progesterone by vaginal suppository and betamimetics to reduce preterm birth in women at risk

Public title

effects of Progesterone by vaginal suppository to reduce preterm birth in women at risk

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: cervical insufficiency, history of premature labor and uterine abnormalities. Exclusion criteria : fetal abnormalities, preeclampsia, and sensitivity to progesterone

Age

From **15 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Science

Street address
Ghafarie street, Birjand

City
Birjand

Postal code

Approval date
2008-09-22, 1387/07/01

Ethics committee reference number
517

Health conditions studied

1

Description of health condition studied
Preterm delivery

ICD-10 code
(O00-O99)

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Number of days delay in delivery of prescribed suppositories

Timepoint
during labor

Method of measurement
Counting the days

Secondary outcomes

empty

Intervention groups

1

Description
In the case group Progesterone supp was administrated every 2days until the end of 34 week of pregnancy.

Category
Treatment - Drugs

2

Description
In the control group betamimetics (syrp. Or tab salbutamol or tab isoxoprin) until the end of 34 week of pregnancy.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Birjand University of Medical Science

Full name of responsible person
Mahboobeh Zangouie

Street address
Birjand University of Medical Science

City
Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Science

Full name of responsible person
Gholamreza Sharifzaadeh

Street address
Birjand University of Medical Science

City
Birjand

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Birjand University of Medical Science

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

Birjand University of Medical Science

Full name of responsible person

Mohammad Hasan Namaaie

Position

PhD Microbiology

Other areas of specialty/work

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Web page address

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