

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Effect of vaginal progesterone on prevention of preterm delivery and neonatal side effects in women at risk for preterm birth

Protocol summary

Semnan University of Medical Sciences

Summary

First step in prevention of preterm delivery is early detection of high risk women. Risk factors of preterm labor birth are: history of preterm labor birth, incompetent cervix and having cerclage, uterine anomalies. Thus we are going to determine if progesterone (vaginal suppository, 400 mg) as a maintenance tocolytic can prevent preterm labor birth in 100 women who are high risk for preterm labor birth and compare the neonatal outcome.

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012273386N2**

Registration date: **2011-04-03, 1390/01/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-03, 1390/01/14

Registrant information

Name

Azam Azargoon

Name of organization / entity

Semnan University of Medical Sciences

Country

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Phone

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Email address

a-azargoon@sem-ums.ac.ir

Scientific title

Effect of vaginal progesterone on prevention of preterm delivery and neonatal side effects in women at risk for preterm birth

Public title

Effect of vaginal progesterone on prevention of preterm delivery and neonatal side effects in women at risk for preterm birth

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: history of preterm labor birth (having at least one delivery before 37 wks of gestational age), incompetent cervix and having cerclage, uterine anomalies (septate uterus, unicornuate or bicornuate).
exclusion: clinical evidence of chorioamnionitis, contraindication to use of progesterone (allergy to progesterone products, Diabetes, hypertension, hyperthyroidism, heart disease, polyhydramnios, IUGR, multiple pregnancy).

Age

From **16 years** old to **37 years** old

Gender

Female

Recruitment status

Recruitment complete

Funding source

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Basij square

City

Semnan

Postal code

3519899951

Approval date

2010-12-09, 1389/09/18

Ethics committee reference number

3/1/12225

Health conditions studied

1

Description of health condition studied

Preterm Labor Birth

ICD-10 code

O60.1

ICD-10 code description

Preterm labour with preterm delivery

Primary outcomes

1

Description

Preterm Labor Birth

Timepoint

From 16 week to 34 week

Method of measurement

Delivery

Secondary outcomes

1

Description

Necrotising Enteroocolitis

Timepoint

After Birth

Method of measurement

NICU records

2

Description

Intra Cranial Haemorrhage

Timepoint

After Birth

Method of measurement

NICU records

3

Description

Weight less than 2500 g

Timepoint

After Birth

Method of measurement

scale

Intervention groups

1

Description

Vaginal suppositories are given as Placebo in control group

Category

Placebo

2

Description

Suppositories of vaginal Progesterone 400 mg are given in intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Hospital

Full name of responsible person

Dr Raheb Ghorbani

Street address

Emam Hosein square

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Raheb Ghorbani

Street address

Basij square

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr Azam Azargoon

Position

Obstetrics & Gynecology

Other areas of specialty/work

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Person responsible for updating data

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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