

# 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

Iran (Islamic Republic of)

###### Phone

+98 23 1446 3401

###### 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****Street address**

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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*