

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparing the efficacy of vaginal progesterone (cyclogest) versus injection of 17a hydroxyprogesterone caproate ( proluton) in preventing of preterm brth less than 34 weeks gestation in pregnant women with threatend abortion in Arash Hospita

#### Protocol summary

2015-02-07, 1393/11/18

##### Summary

(1)Objectives: compare the effect of intravaginal cyclogest and Proluton treatment on preterm labor in women with threatened abortion reffering to Arash hospital. (2) Design:A randomized clinical trial phase 2, single blind (3) Setting and conduct: Women referring to Arash hospital emergency with the complain of threatened abortion in 20-12 weeks, randomly are divided into two groups of cyclogest or Proluton recievers. (4) Participants including major eligibility criteria: 182 patients will be enrolled in this study by convenience sampling. Exclusion criteria incloud: known systemic disease, fever, and not see the gestational sac yolk sac in weeks 5.5 to 6 weeks of pregnancy or fetus at 6 to 6.5 weeks of gestation or cardiovascular activity at 7 week, short cervical length at 16-24 weeks of gestation or twin pregnancy. (5) Intervention: Group 1 will receive Proluton wth the dose of 250 mg/IM/ weekly and the second group will receive vaginal Cyclogest with the dose of 400 mg/daily. (6) main outcome(measures variables) : two interventional groups will assess in terms of stopping bleeding and uterine gramphay, abortion and pregnancy outcomes up to 34th week of pregnancy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014123120504N1**  
Registration date: **2015-02-07, 1393/11/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Arezoo Esmailzadeh

###### Name of organization / entity

Tehran University of Medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7788 3283

###### Email address

dr.a.esmailzadeh@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research of Tehran University of Medical Science

##### Expected recruitment start date

2014-11-28, 1393/09/07

##### Expected recruitment end date

2015-04-30, 1394/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the efficacy of vaginal progesterone (cyclogest) versus injection of 17a hydroxyprogesterone caproate ( proluton) in preventing of preterm brth less than 34 weeks gestation in pregnant women with threatend abortion in Arash Hospita

##### Public title

effect of progesteron in preterm labor

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

women referring to Arash hospital emergency with the complain of threatened abortion in 20-12 weeks (vaginal bleeding and uterine cramps) incloud the study.  
Exclusion criteria are: known systemic disease; fever; not see the gestational sac yolk sac in 5.5 to 6 weeks of pregnancy; fetus at 6 to 6.5 weeks of gestation; cardiovascular activity at 7 week; short cervical length at 16-24 weeks of gestation; twin pregnancy

### **Age**

No age limit

### **Gender**

Female

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **182**

### **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**

Ethic committee of Tehran University of Medical Science

##### **Street address**

Tehran University of Medical Sciences, Keshavarz blvd., Ghods st.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-06-10, 1393/03/20

#### **Ethics committee reference number**

93/130/556/3

## **Health conditions studied**

### 1

#### **Description of health condition studied**

pre term labor

#### **ICD-10 code**

O60

#### **ICD-10 code description**

Onset (spontaneous) of labour before 37 completed weeks of gestation

## **Primary outcomes**

### 1

#### **Description**

assessment of pre term labor

#### **Timepoint**

after 34 weeks

#### **Method of measurement**

obsaervational

## **Secondary outcomes**

### 1

#### **Description**

abortion

#### **Timepoint**

after 8 weeks of treatment

#### **Method of measurement**

observational

### 2

#### **Description**

lengthh of cervix

#### **Timepoint**

16- 24 weeks

#### **Method of measurement**

sonography

## **Intervention groups**

### 1

#### **Description**

The first group of women who complained of threats to abortion 20-12 weeks (vaginal bleeding and uterine cramps) go to the Arash hospital and how cyclogest intravaginal progesterone 400 mg daily

#### **Category**

Treatment - Drugs

### 2

#### **Description**

The second group of women who complained of threats to abortion 20-12 weeks (vaginal bleeding and uterine cramps) go to the Arash hospital and how to administer intramuscular injections of 250 mg Proloton is once a week

#### **Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Arash hospital

**Full name of responsible person**

Arezoo Esmailzadeh

**Street address**

Arash hospital, Tehranpars, Resalat highway

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Masoudi Yonesian

**Street address**

Tehran University of Medical Sciences, Keshavarz blvd., Ghods st.

**City**

Tehran

**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, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Abootaleb Beigi

**Position**

Specialist of Obstetrics and gynaecology ,prenatology floship

**Other areas of specialty/work**

**Street address**

Arash hospital, Tehranpars, Resalat highway

**City**

Tehran

**Postal code**

**Phone**

+98 21 7788 3283

**Fax**

**Email**

beigi\_a@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Abootaleb Beigi

**Position**

Specialist of Obstetrics and gynaecology ,prenatology floship

**Other areas of specialty/work**

**Street address**

Arash hospital, Tehranpars, Resalat highway

**City**

Tehran

**Postal code**

**Phone**

+98 21 7788 3283

**Fax**

**Email**

beigi\_a@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Arezoo Esmailzadeh

**Position**

MD

**Other areas of specialty/work**

**Street address**

Arash hospital, Tehranpars, Resalat highway

**City**

Tehran

**Postal code**

**Phone**

+98 21 7788 3283

**Fax**

**Email**

dr.a.esmailzadeh@yahoo.com

**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*