

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of the Effects of Vaginal Progesterone (Cyclogest) and Intramuscular Progesterone (Hydroxyprogesterone Caproate) in the Prevention of Preterm Labor

#### Protocol summary

##### Summary

The purpose of this study was to evaluate and to compare the efficacy of vaginal progesterone and intramuscular progesterone in the prevention of preterm delivery. Pregnant women with a risk factor of preterm delivery were enrolled. Women with multiple pregnancy, severe liver disease and sensitivity to hormonal therapy were excluded. The study population was consisted of the pregnant women who admitted to Shahid Sadoughi hospital at gestational age of 16-20 weeks. The required calculated sample size was 76 subjects. Interventions included the prescription of vaginal progesterone or intramuscular progesterone. Interventions were started at gestational age of 16-20 weeks and were followed up till delivery. The primary outcomes were the mean delivery time and the percent of preterm delivery in each group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015040921670N1**

Registration date: **2015-05-05, 1394/02/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-05, 1394/02/15

##### Registrant information

##### Name

Elham Bahrami

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3822 4000

##### Email address

bahrami\_hmrc@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2012-11-21, 1391/09/01

##### Expected recruitment end date

2015-01-20, 1393/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effects of Vaginal Progesterone (Cyclogest) and Intramuscular Progesterone (Hydroxyprogesterone Caproate) in the Prevention of Preterm Labor

##### Public title

the effect of progesterone in the prevention of preterm delivery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: History of preterm delivery; cervix length of <25 mm at gestational age of 16-20 weeks  
Exclusion criteria: Multiple pregnancy; severe liver disease; hypertension; diabetes; cardiovascular disease; thromboembolic disorder; seizures; sensitivity to

hormonal therapy

#### Age

No age limit

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 76

#### 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

Ethical committee of Shahid Sadoughi University of  
Medical Sciences

###### Street address

Shahid Sadoughi University of Medical Sciences,  
Shahid Bahonar Bld., Yazd

###### City

Yazd

###### Postal code

##### Approval date

2012-08-23, 1391/06/02

##### Ethics committee reference number

17/1/107183/پ

### Health conditions studied

#### 1

##### Description of health condition studied

Complications of labour and delivery

##### ICD-10 code

060.1

##### ICD-10 code description

Preterm spontaneous labour with preterm delivery

### Primary outcomes

#### 1

##### Description

Mean delivery time

##### Timepoint

The end of intervention

##### Method of measurement

delivery time in week

### Secondary outcomes

#### 1

##### Description

Drug side effects

##### Timepoint

During intervention

##### Method of measurement

Drug side effects records

#### 2

##### Description

Infant outcomes

##### Timepoint

End of intervention

##### Method of measurement

Infant outcomes records

### Intervention groups

#### 1

##### Description

vaginal progesterone

##### Category

Treatment - Drugs

#### 2

##### Description

intramuscular progesterone

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Shahid Sadoughi Hospital

###### Full name of responsible person

Elham Bahrami

###### Street address

Shahid Sadoughi hospital, Shahid Ghandi Bld., Yazd

###### City

Yazd

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research of Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Amir Houshang Mehrparvar

**Street address**

Shahid Sadoughi University of Medical Sciences, Shahid Bahonar Bld., Yazd

**City**

Yazd

**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 Shahid Sadoughi 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**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Elham Bahrami

**Position**

Ob&Gyn residency

**Other areas of specialty/work****Street address**

Shahid Sadoughi hospital, Shahid Ghandi Bld., Yazd

**City**

Yazd

**Postal code**

8915849988

**Phone**

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bahrami-hmrc@ssu.ac.ir.dr.bahramie7531@gmail.com

**Web page address**

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Elham Bahrami

**Position**

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**Other areas of specialty/work****Street address**

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### Person responsible for updating data

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Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Elham Bahrami

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**Web page address**

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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*