

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

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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