Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Summary

(1)Objectives: compare the effect of intravaginal cyclogest and Proloton treatment on preterm labor in women with threatened abortion refferring 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 Proloton 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 Proloton 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

2015-02-07, 1393/11/18

Registrant information

Name
Arezoo Esmailzadeh
Name of organization / entity
Tehran University of Medical science
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research of Tehran Uviversity 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 progestron 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 Uviversity 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/د

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

lenghth 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
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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
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Position
Specialist of Obstetrics and gynaecology ,prenatology floship

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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