

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of dydrogesterone in prevention of preeclampsia in high-risk pregnancy of primigravidae women that has been referred to gynecology clinic

Protocol summary

Study aim

The effect of dydrogesterone in prevention of preeclampsia in high-risk pregnancy of primigravidae women that has been referred to gynecology clinic

Design

Randomized (random block method), double-blind study, placebo control, single arm trial. The sample size of this study is 168 individuals: divided into 2 groups of 84 people.

Settings and conduct

Amiralmomenin Hospital in Semnan

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women that have aged 18 to 40 years; nulliparous Women; the body mass index is equal to or greater than 30 kg / m². Exclusion criteria: The history of consumption of progesterone supplements in the last 6 months; contraindications for the use of progesterone; use of drugs that induce liver enzymes activation (carbamazepine, phenytoin and rifampin); diagnosis of embryonic anomalies by ultrasound; previous cases of systemic diseases, such as asthma, diabetes, liver and kidney disorders, cardiovascular disease, connective tissue diseases.

Intervention groups

Control group: placebo from the 7th week of pregnancy (it consists of sugar and starch, in terms of shape, size and color, exactly the same as Duphaston®, 3 times a day) until 14-16 weeks of pregnancy. Intervention group: Daily 30 mg dydrogesterone from the 7th week of pregnancy (10 mg Duphaston® tablet manufactured by ABBOTT Heal THCARE, Netherlands, (Importer of Behestan Pharmaceutical Company), 3 times a day) until 14-16th week of pregnancy.

Main outcome variables

Vaginal bleeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N30**

Registration date: **2018-02-18, 1396/11/29**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-18, 1396/11/29**

Update count: **0**

Registration date

2018-02-18, 1396/11/29

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-12, 1396/09/21

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dydrogesterone in prevention of preeclampsia in high-risk pregnancy of primigravidae women that has been referred to gynecology clinic

Public title

The effect of dydrogesterone in prevention of preeclampsia in high-risk pregnancy of primigravidae women that has been referred to gynecology clinic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women that have aged 18 to 40 years Nulliparous
Women The body mass index is equal to or greater than 30 kg / m²

Exclusion criteria:

The history of consumption of progesterone supplements in the last 6 months
Contraindications for the use of progesterone
Use of drugs that induce liver enzymes activation (carbamazepine, phenytoin and rifampin)
Diagnosis of embryonic anomalies by ultrasound
Previous cases of systemic diseases, such as asthma, diabetes, liver and kidney disorders, cardiovascular disease, connective tissue diseases.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **168**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 2). Using Excel software to generate random number tables.

Blinding (investigator's opinion)

Double blinded

Blinding description

To a group of A drug packs and to the second group of B drug packs will be given; thus, the patients and the investigator (the presenter) will be unaware of the treatment group and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2018-02-06, 1396/11/17

Ethics committee reference number

IR.SEMUMS.REC.1396.161

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

O00-O99

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Vaginal bleeding

Timepoint

During pregnancy and after childbirth

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups

1

Description

Control group: placebo from the 7th week of pregnancy (it consists of sugar and starch, in terms of shape, size and color, exactly the same as Duphaston®, 3 times a day) until 14-16 weeks of pregnancy.

Category

Diagnosis

2

Description

Intervention group: Daily 30 mg dydrogesterone from the 7th week of pregnancy (10 mg Duphaston® tablet manufactured by ABBOTT Heal THCARE, Netherlands, (Importer of Behestan Pharmaceutical Company), 3 times a day) until 14-16th week of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Sanam Moradan

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammadreza Asgari

Street address

Semnan University of Medical Sciences, Basij Blvd,
Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

asgari5000@gmail.com

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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Sanam Moradan

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

are20935@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Sanam Moradan

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Fax
Email
are20935@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Hadiseh Jahanpour
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Phone
+98 33451336
Email
are20935@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

Only available to scholars working in academic institutions.

Under which criteria data/document could be used

In case of relevant studies.

From where data/document is obtainable

Sanam Moradan. Amir Al-Momenin Hospital, Mostafa Khomeini Blvd, Semnan. 00989127312407

What processes are involved for a request to access data/document

-

Comments