

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the effect of oral Dydrogesterone (Duphaston) on vaginal bleeding and abortion rate in threatened abortion at first trimester

Protocol summary

Study aim

Evaluation of the effect of oral Dydrogesterone (Duphaston) in threatened abortion at first trimester referring to Mahdiah and Shohada-e-Tajrish Hospitals during the years 2016 and 2017

Design

In this clinical trial, 170 pregnant women aged 18 to 35 years of age eligible for the study are randomly assigned into two groups of oral therapy and control groups, according to the random number table.

Settings and conduct

Pregnant women aged 18 to 35 years old eligible for the study referred to Mahdiah and Shohad-e Tajrish hospitals after obtaining written consent and recording information (age, age, last menstrual period (LMP), gestational age, history of previous pregnancies, vaginal bleeding history in previous pregnancies, vaginal bleeding amount and history of abortion) are randomly divided into two groups of oral dystrogestrone (duphestone) and control, and were monitored for up to 20 weeks. The duration of vaginal bleeding is recorded before and after the study and the occurrence of abortion will record.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18 to 35 years old; singleton pregnancy; symptoms and signs of threaten abortion in the first trimester; an ultrasound report with viable fetus Exclusion criteria: Presence of underlying conditions such as high blood pressure and diabetes; allergies to dystrogestrone components

Intervention groups

The case group: Treatment with oral dydrogesterone (Duphaston®, Solvay company, USA), 40 mg in the first dose, followed by 10 mg every eight hours until the bleeding was discontinued and the relative rest in the bed. The control group: Only conservative treatment with relative rest in the bed

Main outcome variables

Duration of vaginal bleeding and the occurrence of

abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120918010876N5**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Masumeh Mirza Moradi

Name of organization / entity

Prinatology department of Mahdiah hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 6263

Email address

m-bakhtiyari@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-21, 1396/08/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral Dydrogesterone (Duphaston) on vaginal bleeding and abortion rate in threatened abortion at first trimester

Public title

Evaluation of the effect of oral Dydrogesterone (Duphaston) in threatened abortion at first trimester

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women in the first trimester Presence of symptoms and signs of threatened abortion Singleton pregnancy Having an ultrasound report with viable fetus

Exclusion criteria:

The presence of underlying illnesses such as high blood pressure, diabetes Known allergy to dystrogesterone components

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

Use the random numbers table and randomization according to the the order of entering to the study

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**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-11-21, 1396/08/30

Ethics committee reference number

IR.SBMU.MSP.REC.1396.600

Health conditions studied**1****Description of health condition studied**

Threatened abortion

ICD-10 code

O20.0

ICD-10 code description

Threatened abortion

Primary outcomes**1****Description**

Abortion

Timepoint

Daily check from the beginning of the study up to 20 weeks

Method of measurement

Observation and clinical symptoms

2**Description**

Vaginal bleeding

Timepoint

At the beginning of the study and after starting the study until the end of the study

Method of measurement

Amount and number of sanitary pads

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Treatment with oral dydrogesterone (Duphaston®, Solvay company, USA), 40 mg in the first dose, followed by 10 mg every eight hours until the bleeding was discontinued and the relative rest in the bed

Category

Treatment - Drugs

2**Description**

Control group: Only conservative treatment with relative rest in the bed

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Dr. Masoome Mirzamoradi

Street address

Mahdieh Hospital, Shoosh Sq.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

mahdiyeh-hospital@yahoo.com

2

Recruitment center

Name of recruitment center

Shohada-e Tajrish Hospital

Full name of responsible person

Dr. Masoome Mirzamoradi

Street address

Tajrish Sq.

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ali Ziayee

Street address

Next to Taleghani Hospital, Shahid Arabi St., Yemen St., Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Masoome Mirzamoradi

Position

Perinatologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Mahdieh Hospital, Shoosh Sq.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 6263

Fax

Email

drmoradi000@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Masoome Mirzamoradi

Position

Perinatologist

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Specialist

Other areas of specialty/work

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Street address

Mahdieh Hospital, Shoosh Sq.

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Phone

+98 21 5506 6263

Fax**Email**

drmoradi000@yahoo.com

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Gynecology and Obstetrics

Street address

Mahdieh Hospital, Shoosh Sq.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 6263

Email

dr.taherian.z1362@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No need for publication

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Kobra Taherian

Position

Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work