

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison between the effect of Dydrogesterone and Cyclogest intake on consequences of pregnancy in threatend abortion.

Protocol summary

Study aim

The Comparison between the effect of Dydrogesterone and Cyclogest intake on pregnancy in case of threatened abortion

Design

Randomized, parallels clinical trial.

Settings and conduct

Participant 160 pregnant women with threatened abortion between 6 to 13 weeks of pregnancy referred to Kowsar Hospital who are willing to participate in the study were selected and put randomly in one of the groups A and B (Each group, 80 patients). For group A, Cyclogest vaginal suppository 400 mg daily and for group B, Didrogesterone tablet 20 mg daily up to the end of 16 week of pregnancy. Patients are evaluated up to 28 weeks monthly and until 36 weeks every two weeks and then weekly until delivery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 6 to 13 weeks; Observation of fetal heart rate; vaginal bleeding; uterine closure; uterine or fetal anomalies. Exit criteria: unwillingness of the patient; lack of fetal heart rate; severe liver problems; epilepsy; diabetes; hypertension.

Intervention groups

Intervention group1: Cyclogest vaginal suppository made by Abourihan Company, is given 400 milligrams per day from the initial of the study up to the end of 16 weeks of pregnancy. Intervention group2: Dydrogestrone tablet made by Abourihan Company, is given 20 milligrams per day from the initial of the study up to the end of 16 weeks of pregnancy.

Main outcome variables

Preterm labor: Preeclampsia: Gestational diabetes: Low birth weight: Abortion less than 20 weeks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120104008611N8**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Hamideh Pakniat

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 282242452

Email address

hpakniat@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2017-07-23, 1396/05/01

Trial completion date

2018-09-21, 1397/06/30

Scientific title

The comparison between the effect of Dydrogesterone and Cyclogest intake on consequences of pregnancy in threatend abortion.

Public title

The effect of Dydrogesterone and Cyclogest on threatend abortion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age 6 to 13 weeks Observation of fetal heart rate Vaginal bleeding Uterine anomalies Fetal anomalies

Exclusion criteria:

Patient unwillingness Breast carcinoma Lack of fetal heart rate Severe liver problems Genital carcinoma Thromboembolic disorders Epilepsy Diabetes Hypertension

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Not 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**

Ethics committee of Qazvin University of Medical Sciences

Street address

Vice-Chancellor for Research of Qazvin University of Medical Sciences, Valiasr street, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Approval date

2018-04-30, 1397/02/10

Ethics committee reference number

IR.QUMS.REC.1397.018

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**

Threatened abortion

Timepoint

Before intervention and 2 weeks after the completion of the intervention

Method of measurement

Weekly visit

Secondary outcomes**1****Description**

Preeclampsia

Timepoint

Up to 28 weeks monthly and until 36 weeks every two weeks and thereafter weekly until delivery

Method of measurement

Mercury Barometer

2**Description**

Gestational Diabetes

Timepoint

Up to 28 weeks monthly and until 36 weeks every two weeks and then weekly until delivery

Method of measurement

Glucose tolerance test

3**Description**

Preterm labor

Timepoint

Up to 28 weeks monthly and until 36 weeks every two weeks and then weekly until delivery

Method of measurement

Tocometry of uterus and delivery before 37 weeks of pregnancy

4**Description**

Low birth weight

Timepoint

Weight immediately after birth

Method of measurement

Pediatric scales

5**Description**

Abortion under 20 weeks of pregnancy

Timepoint

Every week from the start of the intervention up to 20 weeks of pregnancy

Method of measurement

Questionnaire

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

Intervention group1: Progesterone vaginal suppository made by Abourihan Company, 400 milligrams only once per day since the initial of the study up to 16 weeks of pregnancy

Category

Treatment - Drugs

2**Description**

Intervention group2: Didrogestosterone tablet made by Abourihan Company, 10mg twice a day (10 mg every 12 hours) since the initial of the study up to 16 weeks of pregnancy

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kowsar hospital

Full name of responsible person

Dr Hamide pakniat

Street address

Taleghani Blvd, Valiasr

City

Qazvin

Province

Qazvin

Postal code

3415613176

Phone

+98 28 3323 6374

Fax

+98 28 3323 6374

Email

pakniat110@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

Street address

Vice-Chancellor for Research of Qazvin University of Medical Sciences, Valiasr street, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Phone

+98 28 3333 6001

Email

research.dpt@qums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Dr nushin kashanipoor

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kowsar Hospital, Taleghani St, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Phone

+98 28 3333 3006

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Hamideh Pakniat

Position

Asistant Professor, Department of Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kowsar Hospital, Taleghani St, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Phone

+98 28 3323 6374

Email

pakniat110@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Hamideh Pakniat

Position

Asistant Professor, Department of Obstetrics and Gynecology Qazvin University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kowsar Hospital, Taleghani St, Qazvin, Iran

City

Qazvin

Province

Qazvin

Postal code

3415613176

Phone

+98 28 3223 6374

Email

pakniat110@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

Information is the most commonly used questionnaire, which is a statistical analysis

When the data will become available and for how long

After completing the data analysis

To whom data/document is available

All the readers of the article

Under which criteria data/document could be used

For scientific purposes, it is important to note the source

From where data/document is obtainable

Library of Qazvin University of Medical Sciences

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

It is possible to access the Thesis Principle

Comments