

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

##### Study aim

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

##### Design

Two parallel groups randomized trial, not blinded, single center

##### Settings and conduct

200 pregnant women threatened with abortion from kowsar hospital which were satisfied to participate in the study were selected and randomly allocated in one of the groups A and B. For the A group micronized progesterone was prescribed and for the group B Didrogesterone tablet was prescribed.

##### Participants/Inclusion and exclusion criteria

Gestational age 6 to 13 weeks; Observation of fetal heart rate; Vaginal bleeding; Absence of uterine anomalies; Absence fetal anomalies

##### Intervention groups

Intervention group 1: Didrogesterone tablet made by Abourihan Company, 10 mg twice a day (10 mg every 12 hours ) since the initial of the study up until one week after bleeding and intervention group 2: Progesterone capsule made by Tansim Company, 100 mg twice a day since the initial of the study up until one week after bleeding

##### Main outcome variables

Preeclampsia; Gestational Diabetes; Preterm labor; Low birth weight; Abortion under 20 weeks of pregnancy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120104008611N10**  
Registration date: **2020-01-31, 1398/11/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-31, 1398/11/11**

Update count: **0**

##### Registration date

2020-01-31, 1398/11/11

##### 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

2019-10-22, 1398/07/30

##### Expected recruitment end date

2020-10-21, 1399/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

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

##### Public title

The effect of Dydrogesterone and micronized progesterone on threatend abortion

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Gestational age 6 to 13 weeks  
Observation of fetal heart rate  
Vaginal bleeding  
Absence of uterine anomalies  
Absence fetal anomalies

### Exclusion criteria:

Breast carcinoma  
Severe liver problems  
Genital carcinoma  
Thromboembolic disorders  
Epilepsy  
Diabetes  
Hypertension

## Age

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

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **200**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants were randomly assigned to one of two study groups using the random number table and received group-based intervention. The medications include Dydrogesterone and Lutogel capsules (micronized progesterone), which are encoded in separate envelopes and are used in addition to patient education on the envelope and delivered to participants.

## 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

2019-11-07, 1398/08/16

## Ethics committee reference number

IR.QUMS.REC.1398.183

## 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

Preeclampsia

#### Timepoint

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

#### Method of measurement

Sphygmometer

### 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

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group 1: Didrogesterone tablet made by Abourihan Company, 10 mg twice a day (10 mg every 12 hours ) since the initial of the study up until one week after bleeding

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Intervention group 2: Progesterone capsule made by Tansim Company,100 mg twice a day since the initial of the study up until one week after bleeding

##### **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 Hamide pakniat

###### **Position**

Assistant Professor of Obstetrics and Gynecology

###### **Latest degree**

Specialist

###### **Other areas of specialty/work**

Gynecology and Obstetrics

###### **Street address**

Qazvin

###### **City**

Qazvin

###### **Province**

Qazvin

###### **Postal code**

3415613176

###### **Phone**

+98 28 3323 6374

###### **Email**

pakniat110@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr Hamide Pakniat

**Position**

Assistant Professor of Obstetrics and Gynecology

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Taleghani Blvd, Valiasr

**City**

Qazvin

**Province**

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**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 Hamide Pakniat

**Position**

Assistant Professor of Obstetrics and Gynecology

**Latest degree**

Specialist

**Other areas of specialty/work**

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## 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**

Because sharing participants' personal information is not a goal of our study.

**Study Protocol**

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

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is 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**

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

**Data Dictionary**

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

**Title and more details about the data/document**

After obtaining informed consent, patient information was recorded in the questionnaire and after receiving the drugs, the results were again recorded in the questionnaire for statistical analysis. This sharing will occur after the end of the study.

**When the data will become available and for how long**

Starting 1 years after publication.

**To whom data/document is available**

Only available for people working in academic institutions

**Under which criteria data/document could be used**

Statistical analysis will then be used by the statistical consultant and the documentation results will be identified.

**From where data/document is obtainable**

Applicants should contact Dr Hamideh Pakniat, the project manager, to obtain the required documentation or data. Ways of communicating are by email, by phone, or by visiting the Kowsar Qazvin Training Center. Postal address: Kowsar Hospital, Taleghani Street, Qazvin  
Email: pakniat110@yahoo.com Phone no: 028- 33236378

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

The applicant must first notify the project manager by email. Then, as soon as possible, in less than a week, the Designer will provide the requested information at the discretion.

**Comments**