

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Vaginal Progesterone and Oral Micronized Progesterone on Pregnancy Outcomes in Women with Threatened Miscarriage

Protocol summary

Study aim

the effect of micronized progesterone and progesterone suppository on pregnancy survival compares in pregnant women threatened with abortion.

Design

Two parallel groups randomized trial, not blinded, single center

Settings and conduct

170 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 progesterone suppository was prescribed.

Participants/Inclusion and exclusion criteria

Pregnant women with a gestational age of more than 6 weeks and less than or equal to 13 weeks, presenting with a closed cervix on vaginal examination and exhibiting symptoms of threatened miscarriage, such as bloody discharge or uterine bleeding with or without pain, were considered eligible for inclusion in the study. Exclusion criteria included absence of fetal heartbeat, confirmation of fetal or uterine abnormalities, multiple pregnancy or hydatidiform pregnancy.

Intervention groups

to one group progesterone suppository is given 400 milligrams per day and to the other group 100 milligrams of progesterone capsule is given per day.

Main outcome variables

Pregnancy residues ;pre term delivery ; complications of post consumption of medicines.

General information

Reason for update

Due to the coincidence of the sampling with the corona pandemic, the sampling has started with a delay. In addition, during the research, changes were made in the way it was done, and we are required to record these

changes and approve them.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120104008611N9**

Registration date: **2019-05-12, 1398/02/22**

Registration timing: **prospective**

Last update: **2024-10-19, 1403/07/28**

Update count: **1**

Registration date

2019-05-12, 1398/02/22

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

2018-04-21, 1397/02/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

2022-02-01, 1400/11/12

Actual recruitment end date

2022-11-06, 1401/08/15

Trial completion date

2023-09-05, 1402/06/14

Scientific title

Comparison of Vaginal Progesterone and Oral Micronized

Progesterone on Pregnancy Outcomes in Women with Threatened Miscarriage	
Public title	Comparison of the effect of two progesteron drugs in protection of abortion
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Gestational age 6 to 13 weeks Apearance of fetal heart rate Uterine bleeding Closed uterine orifice Exclusion criteria: Having embryonic or uterine anomalies in ultrasound Multi fetal Hydatidiform mole A known underlying disease in mother Patients who have been treated by a specific medication to treat abortion the absence of fetal heartbeat, malignancy presence of anorectal disorders genital tract infections endocrine disorders cardiovascular disorders progesterone hypersensitivity refusal to participate
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: 170
Randomization (investigator's opinion)	Randomized
Randomization description	Medications are encoded in separate envelopes and delivered to the participants.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Qazvin University of Medical Sciences
Street address	Bahonar Blvd, Qazvin, Iran
City	Qazvin

Province	Qazvin
Postal code	3419759811
Approval date	2018-03-12, 1396/12/21
Ethics committee reference number	IR.QUMS.REC.1396.498
Health conditions studied	
<u>1</u>	
Description of health condition studied	Abortion
ICD-10 code	-
ICD-10 code description	-
Primary outcomes	
<u>1</u>	
Description	Abortion
Timepoint	From the start of the intervention up to end of pregnancy
Method of measurement	Weekly visit until the end of bleeding
Secondary outcomes	
<u>1</u>	
Description	Preeclampsia
Timepoint	Up to 28 weeks monthly until 36 weeks every two weeks and thereafter weekly until delivery
Method of measurement	Mercury pressure gauge
<u>2</u>	
Description	Gestational Diabetes
Timepoint	Up to 28 weeks monthly until 36 weeks every two weeks and thereafter weekly until delivery
Method of measurement	Glucose tolerance test
Intervention groups	
<u>1</u>	
Description	Intervention group: Progesterone suppository 400 milligrams per day
Category	

Treatment - Drugs

2

Description

Intervention group: Progesterone capsule 100 mg per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Hamide Pakniat

Street address

Taleghani Blvd, Valiasr

City

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Qazvin

Postal code

3415613176

Phone

+98 28 3223 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

Bahonar Blvd, Qazvin, Iran

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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

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 Hamideh Pakniat

Position

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

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Hamideh Pakniat

Position

Associated Professor, Department of Obstetrics and Gynecology

Latest degree

Specialist

Other areas of specialty/work

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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

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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

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

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

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

Path analysis

From where data/document is obtainable

Dr Hamideh Pakniat executor of plan

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

The email will be submitted to the project promoter at
the discretion of the information.

Comments