Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 compars 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)

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+98 282242452

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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

1

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

1

Description of health condition studied
Abortion
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

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

1

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

2

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

1

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Amir Peymani
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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
Asistant Professor, Department of Obstetrics and Gynecology Qazvin University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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