Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 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
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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

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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 Paknat, 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