Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of the efficacy of two therapeutic methods of use of dydrogesterone and vaginal progestrein as a luteal cycles support in Assisted Reproductive Technology (ART) in patients referring to Fateme Zahra infertility center in Babol

Protocol summary

Study aim
Comparison of the efficacy of two therapeutic methods of use of dydrogesterone and vaginal progestrein as a luteal cycles support in Assisted Reproductive Technology (ART)

Design
A single-blind clinical trial with parallel groups. 210 patients have randomly divided into intervention and control groups with a table of random numbers and Randomizer software.

Settings and conduct
The population of this study was infertile women aged 20-40 years old who referred to Fatemeh Al-Zahra infertility center in Babol. Patients are randomly divided into two groups with a table of random numbers by computer. The first intervention group receives 400 mg vaginal suppository once a day. The second intervention group receives oral progesterone-duphaston 20 mg twice a day. The medications are prepared quite similar in appearance (color and shape), sealed in opaque envelopes with consecutive numbers. The researcher is aware of numbers

Participants/Inclusion and exclusion criteria
Inclusion criteria: 20-40 years old, Body Mass Index 30-18 Kg/m2, Endometrium Thickness 7-14 mm
Exclusion criteria: Abnormal prolactin serum level and abnormal thyroid function test, Diminished ovarian reserve (baseline FSH level >10 IU/mL)

Intervention groups
Control group: Receiving 400 mg vaginal suppository once a day Intervention group: Receiving oral progesterone-duphaston 20 mg twice a day

Main outcome variables
Determining the incidence of pregnancy in two methods of dystrogesterone and vaginal progesterone

General information

Reason for update
Sampling completion date

Acronym

IRCT registration information
IRCT registration number: **IRCT20170205032406N2**
Registration date: **2018-10-15, 1397/07/23**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-13, 1402/10/23**
Update count: **2**

Registration date
2018-10-15, 1397/07/23

Registrant information

Name
Maryam Javadian Kootenaei

Name of organization / entity
Babol University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 11 3334 2334

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-02, 1397/07/10

Expected recruitment end date
2020-02-29, 1398/12/10

Actual recruitment start date
2018-10-02, 1397/07/10

Actual recruitment end date

2020-02-29, 1398/12/10

Trial completion date

2020-02-29, 1398/12/10

Scientific title

Comparison of the efficacy of two therapeutic methods of use of dydrogesterone and vaginal progestrein as a luteal cycles support in Assisted Reproductive Technology (ART) in patients referring to Fateme Zahra infertility center in Babol

Public title

The effect of dydrogesterone and vaginal progestrein in support of artificial reproduction techniques

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20-40 years old Body Mass Index 18-30 kg/m2 Endometrium Thickness 7-14 mm

Exclusion criteria:

Abnormal prolactin serum level and abnormal thyroid function test Diminished ovarian reserve (baseline FSH level >10 IU/mL)

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **210**

Actual sample size reached: **207**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients into two intervention groups Patients are randomly divided into two groups A (dydrogesterone), B (vaginal progestin) with a table of random number s (a random number table is a collection of numbers that are generated without a specific pattern or order and completely randomized, then samples are randomly selected by Randomizer software.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants are unaware of the type of intervention (dydrogesterone or vaginal progestin) given to every participant. The medications are prepared quite similar in appearance (color and shape), sealed in opaque envelopes with consecutive numbers. The researcher is aware of numbers.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University Of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Approval date

2018-09-16, 1397/06/25

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.151

Health conditions studied

1

Description of health condition studied

In vitro fertilization

ICD-10 code

N98.2

ICD-10 code description

Complications of attempted introduction of fertilized ovum following in vitro fertilization

Primary outcomes

1

Description

Pregnancy

Timepoint

Once a week after embryo transfer into the patient

Method of measurement

The blood hCG test

Secondary outcomes

1

Description

Preterm delivery

Timepoint

Every two weeks from the twentieth week of pregnancy

Method of measurement

Patient visit and record uterine contractions

2

Description

Amount of live birth

Timepoint

Every two weeks from twenty-eighth week of pregnancy

Method of measurement

Patient visit and record baby's birth

3

Description

Abortion

Timepoint

Six weeks after intervention

Method of measurement

Sonography and pregnancy test

Intervention groups

1

Description

Control group: Receives 400 mg vaginal suppository once a day began on the day of oocyte retrieval and was continued up to 12 weeks of pregnancy.

Category

Treatment - Drugs

2

Description

Intervention group: receives oral progesterone-duphaston 20 mg twice a day. began on the day of oocyte retrieval and was continued up to 12 weeks of pregnancy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & infertility hospital

Full name of responsible person

Dr. Maryam Javadian Kotenae

Street address

Noshirvani street, Fatemehzahra Fertility & infertility hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Shahla Yazdani

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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
There is still no plan for its puplish.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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