Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Evaluation and comparison of luteal phase support with vaginal and oral progesterone in IUI

Protocol summary

Study aim
Evaluation and comparison of luteal phase support with vaginal and oral progesterone in IUI

Design
Interventional clinical trial with control and parallel groups, non-blind, randomized, phase 2 will performed on 288 patients. Randomization will performed using random number table.

Settings and conduct
The objective of this study is Evaluation and comparison of luteal phase support with vaginal and oral progesterone in IUI in Kernan in 2022. Study population: Infertile women 18 to 40 years of age with unexplained infertility, mild male infertility, or due to polycystic ovary syndrome who have not responded to drug treatment alone and are candidates for intrauterine insemination. Study groups: Intervention and control groups. Sample size: 288 women. This is a randomized not blinded trial, in one center, in phase 2 study. Setting and conduct: Infertile women who are candidates for IUI after obtaining informed consent randomized into intervention and control groups.

Participants/Inclusion and exclusion criteria
Infertile women 18 to 40 years of age with unexplained infertility, mild male infertility, or due to polycystic ovary syndrome who have not responded to drug treatment alone and are candidates for intrauterine insemination.

Intervention groups
In the intervention group, after intrauterine insemination, 10 mg of oral dydrogesterone (Duphaston) is used three times a day to support the luteal phase. In the control group, progesterone suppository called vaginal cyclogest 400 micrograms is prescribed twice a day.

Main outcome variables
Chemical pregnancy, clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151004024335N5**
Registration date: **2022-08-09, 1401/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-09, 1401/05/18**
Update count: **0**

Registration date
2022-08-09, 1401/05/18

Registrant information

Name
robabe hoseinisadat

Name of organization / entity
infertility institute center of shahid sadughi

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of luteal phase support with vaginal and oral progesterone in IUI

Public title
Evaluation and comparison of luteal phase support with vaginal and oral progesterone in IUI in Kernan in 2022
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women with unexplained infertility Infertility with a mild male factor Infertility due to polycystic ovary syndrome who have not responded to drug treatment alone Age 18 to 40 years
Exclusion criteria:
Three times more history of unsuccessful intra uterine sperm insemination treatment azoospermia or Severe spermogram disorder Presence of endocrine diseases such as diabetes and severe thyroid disease
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **288**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was simple, individual, not blinded, using a random number table.
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 comittee of Kerman University of Medical Sciences
Street address
Ibn Sina Street, Jahad Boulevard, Somayeh Road (Tahmasebabad)
City
kerman
Province
Kerman
Postal code
7619813159
Approval date
2022-07-19, 1401/04/28
Ethics committee reference number
IR.KMU.AH.REC.1401.072

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N98.9
ICD-10 code description
Complication associated with artificial fertilization, unspecified

Primary outcomes

1

Description
Chemical pregnancy
Timepoint
14 days after embryo transfer
Method of measurement
Measurement of serum beta-HCG

Secondary outcomes

1

Description
Clinical pregnancy
Timepoint
Five weeks after embryo transfer
Method of measurement
Transvaginal ultrasound

2

Description
miscarriage rate
Timepoint
miscarriages before 20 weeks gestation
Method of measurement
Contact patients at the 20th week of pregnancy

Intervention groups

1

Description
Intervention group: Intervention group: To start the IUI cycle, women are given ovulation-stimulating drugs in the form of letrozole or clomiphene tablets for five days from the third day of the menstrual cycle. Then, from the eighth day, the gonadotropin cycle starts with a dose of 150-175 units. On the eleventh day of the menstrual cycle, transvaginal ultrasound is performed to monitor the follicle. Depending on the size of the follicle, the drug is continued and the ultrasound is repeated until one or

two follicles reach a size of 18 mm. If more than two follicles grow due to increased risk of multiple pregnancy or ovarian hyperstimulation, the cycle will be canceled. When the follicle size reaches 18 mm, 10,000 units of human chorionic gonadotropin (HCG) are used to stimulate ovulation. 36 hours after HCG injection, the partner's sperm is prepared by the infertility center laboratory and inseminated into the endometrial cavity with a sterile catheter by the infertility fellowship. Patients are then randomly divided into two groups. In the intervention group, which will consist of 144 women, oral diderogesterone tablets under the Dofaston brand are given as 10 mg three times a day and continue until the 11th week of pregnancy.

Category

Treatment - Drugs

2

Description

Control group: In the control group, after intrauterine insemination of sperm, a progesterone suppository called vaginal cyclogest 400 micrograms is administered twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Infertility Center

Full name of responsible person

Dr Robabe Hosseinisadat

Street address

Imam Khomeini Highway, Afzalipour Hospital

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+98 34 3132 8486

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robabehosseinisadat@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Research Assistant, Kerman University of Medical Sciences

Street address

Ibn Sina Street, Jahad Boulevard, Somayeh Road (Tahmasebabad)

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Robabe Hosseinisadat

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

infertility

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Robabe Hosseinisadat

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
infertility

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Person responsible for updating data

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Position
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Subspecialist

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
The final result of the study will be published and there is no need to share individual participants' data

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

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

Informed Consent Form
Undecided - It is not yet known if there will be 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