

# 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)

###### Phone

+98 35 3824 7085

###### Email address

robabehoseini@ssu.ac.ir

##### 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 Kerman 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 committee of Kerman University of Medical Sciences

**Street address**

Ibn Sina Street, Jihad 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

##### City

kerman

##### Province

Kerman

##### Postal code

۷۶۱۶۹۱۳۹۱۱

##### Phone

+98 34 3132 8486

##### Email

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, Jihad Boulevard, Somayeh Road (Tahmasebabad)

#### City

kermman

#### Province

Kerman

#### Postal code

7619813159

#### Phone

+98 34 3226 3815

#### Email

robabehosseinisadat@yahoo.com

#### 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

Imam Khomeini Highway, Afzalipour Hospital

##### City

kerman

##### Province

Kerman

##### Postal code

7616913911

##### Phone

+98 34 3132 8486

##### Email

robabehosseinisadat@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Robabe Hosseinisadat

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Assistant Professor

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**Person responsible for updating data**

**Contact**

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Kerman University of Medical Sciences

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**Email**

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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