

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

**The effect of luteal phase support by a progestogen drug (cyclogest) on pregnancy rates of stimulated IUI cycles of 98 infertile couples (study group) with unexplained infertility that were compared with stimulated IUI cycles of 102 infertile couples (control group) without drug taking for luteal phase support**

### Protocol summary

#### Summary

Two- hundred couples , who referred to Mirza koochak khan Hospital with unexplained infertility (UEI) , who underwent 511 consecutive stimulated IUI cycles. Clomiphene citrate (c.c) and human Menopausal Gonadotropin (h M G) were used for ovulation induction. Inclusion criteria: infertile women with UEI / normal semen analysis based on World Health Organization criteria / normal early follicular phase ultrasound / normal FSH and LH (<10 IU/L), midluteal phase serum P >20 nmol/L / patent tubes and normal uterine cavity confirmed with hysterosalpingography. The patients were excluded from the study if the female partners had age > 36 years old, diminished ovarian reserve (basal FSH level >10 IU/ L), one ovary, polycystic ovaries on ultrasound examination, previous surgery on ovaries, endometriosis and any type of endocrine disease. After IUI, the patients were randomized into the two groups. The study group (n=98) received intra vaginal P (Cyclogest) for LPS. The patients randomized into the control group (n=102) received no drug for LPS. Main outcome Measures are Clinical Pregnancy rate (PR) and live birth rate (BR) per cycle and patient.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT138901283737N1**

Registration date: **2010-04-28, 1389/02/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2010-04-28, 1389/02/08

#### Registrant information

##### Name

Mahbod Ebrahimi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8889 7761

##### Email address

maebrahimi@rasi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University/Mirza koochak khan Hospital

#### Expected recruitment start date

2007-09-01, 1386/06/10

#### Expected recruitment end date

2008-11-29, 1387/09/09

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of luteal phase support by a progestogen drug (cyclogest) on pregnancy rates of stimulated IUI cycles of 98 infertile couples (study group) with unexplained infertility that were compared with stimulated IUI cycles of 102 infertile couples (control group) without drug

taking for luteal phase support

**Public title**

Increase in pregnancy rate of infertile couples

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria:infertile couples with unexplained infertility / normal semen analysis based on World Health Organization criteria /normal early follicular phase ultrasound / normal FSH and LH (<10 IU/L), midluteal phase serum P >20 nmol/L/patent tubes and normal uterine cavity confirmed with hysterosalpingography. The unexplained infertile patients were excluded from the study if the female partners had age> 36 years old, diminished ovarian reserve (basal FSH level>10 IU/ L), one ovary, polycystic ovaries on ultrasound examination, previous surgery on ovaries, endometriosis and any type of endocrine diseases.

**Age**

From **18 years** old to **36 years** old

**Gender**

Both

**Phase**

0

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tehran Medical Science University

**Street address**

Pour sina Ave/ Tehran

**City**

Tehran

**Postal code**

00982188915959

**Approval date**

empty

**Ethics committee reference number**

222

**Health conditions studied****1****Description of health condition studied**

Female infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

**Primary outcomes****1****Description**

pregnancy rate

**Timepoint**

monthly

**Method of measurement**

pregnancy rate percentile/ pregnancy will be confirmed by serum sample test

**Secondary outcomes****1****Description**

live birth rate

**Timepoint**

9 months

**Method of measurement**

live birth rate percentile in each groups

**Intervention groups****1****Description**

in study group:Cyclogest/400 mg every night/in luteal phase/ if pregnancy happen, this drug will continue till 10 weeks/ if pregnancy does not happen, the drug will continue till14 nights.

**Category**

Treatment - Drugs

**2****Description**

in control group: no drug receiving in luteal phase.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mirza koochak khan Hospital

**Full name of responsible person**

Mahbod Ebrahimi.M.D

**Street address**

Ostad Nejatollahi Ave/ Tehran

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran Medical Sciences University

**Full name of responsible person**

Firoozeh AkbariM.D

**Street address**

Pour sina Ave/ Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran Medical Sciences University

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran Medical Sciences University

**Full name of responsible person**

Firoozeh Akbari M.D

**Position**

Faculty member

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*