

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of effect of ovarian stimulation protocol on incidence of luteinized unruptured follicle syndrome in infertile women undergoing induction ovulation and intrauterine insemination

Protocol summary

Summary

Luteinized unruptured follicle syndrome is considered as a cause of ovulation failure and a subtle cause of infertility. As regard of possibility of interference of clomiphene citrate on etiology of LUF and so far few studies have investigated incidence of LUF and relation with follicular size ,hormonal profile (luteal phase progesterone,FSH,LH)and endometrial thickness in other ovarian stimulation regimens,this study is designed with purpose of evaluation and comparison of LUF related factors in eligible infertile women undergoing two stimulation protocols (clomiphene+HMG)and (letrozole+HMG)and IUI.A total of 180 infertile women 18-35years old with pco,unexplained or male factor infertility after first routine evaluation are included.patients in two equal groups are administered tablet clomiphene citrate 100mg/d or letrozole 5mg/d orally on 3-7 days of cycle and HMG 75IU/d IM from 8 day of cycle.Patients are monitored by vaginal sonography until one follicle reaches>> 18mm.Then HCG 10000IU IM is administered and IUI is performed after 38-40 hours.Transvaginal sonography is performed in HCG day ,before IUI and 5-6 days after IUI.According to results of sonographies and luteal phase progesterone ,LUF or ovulation is diagnosed.Then patients are followed 14 days after IUI by β hcg.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091019113N1**

Registration date: **2014-09-29, 1393/07/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

Name

Mansooreh Pejmanmanesh

Name of organization / entity

Mirza Koochak Khan Hospital-Tehran University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21888977614

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m-pejmanmanesh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of ovarian stimulation protocol on incidence of luteinized unruptured follicle syndrome in infertile women undergoing induction ovulation and intrauterine insemination

Public title

effect of ovarian stimulation drugs on incidence of

unruptured follicle

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria: 1-infertile women 18-35years old candidate for IUI 2-infertility causes:pco,unexplained infertility,male factor Exclusion criteria: 1-hyper prolactinemia,hypo and hyperthyroidism,ovarian cyst,NSAID users,uterus and tubal malformation 2-OHSS

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

corner of Taleghani St, Ghods St, Keshavarz Boolvar

City

Tehran

Postal code

Approval date

2014-09-03, 1393/06/12

Ethics committee reference number

/93/1202/130/ص

Health conditions studied

1

Description of health condition studied

luteinized unruptured follicle

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

2

Description of health condition studied

luteinized unruptured follicle

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

Primary outcomes

1

Description

luteinized unruptured follicle

Timepoint

5-6 days after IUI

Method of measurement

sonography+ serum progesterone(ng/ml)

Secondary outcomes

1

Description

follicular size

Timepoint

every other day from 10 day of cycle

Method of measurement

vaginal sonography

2

Description

serum progesterone

Timepoint

5-6 days after IUI

Method of measurement

blood test

3

Description

ovulation

Timepoint

before and 5-6 days after IUI,

Method of measurement

vaginal sonography

4

Description

pregnancy

Timepoint

14days after IUI

Method of measurement

βhcg blood test

5

Description

FSH

Timepoint

2-3 day of cycle before included in study

Method of measurement

blood test

6

Description

infertility cause

Timepoint

before included in study

Method of measurement

clinician judgement

7

Description

Endometrial thickness

Timepoint

every other day from 10 day of cycle

Method of measurement

vaginal sonography

8

Description

LH

Timepoint

2-3day of cycle before included in study

Method of measurement

blood test

Intervention groups

1

Description

Tab clomiphene citrate 100mg/d orally on 3-7 days of cycle in group1 Amp HMG 75IU/d IM from 8 day of cycle in group1 Amp HCG 10000IU IM when follicular diameter >>18mm in group1

Category

Treatment - Drugs

2

Description

Tab letrozole 5mg/d orally on 3-7 days of cycle in group 2 Amp HMG 75IU/d IM from 8 day of cycle in group 2 Amp HCG 10000IU IM when follicular diameter >>18mm in group2

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mirza koochak khan Hospital.Tehran Universsity Of Medical Sciences

Full name of responsible person

Dr.Mansoorreh Pejmanmanesh Infertility and IVF fellowship assistant

Street address

North Ostad Nejatollahi St, Karimkhan Zand Av,Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Dr.Masood Yoonesian

Street address

Central Organization of University, corner of Ghods St, Keshavarz Boolvar

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University Of Medical Sciences

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

IVF ward, Mirza Koochakkhan Hospital, Tehran University Of Medical Sciences

Full name of responsible person

Dr.Mansoorreh Pejmanmanesh

Position

Infertility fellowship assistant

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

IVF ward-Mirza Koochakkhan Hospital-Tehran
University Of Medical Sciences

Full name of responsible person

Dr.Mansoorreh Pejmanmanesh

Position

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Person responsible for updating data

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Web page address

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