Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of effect of ovarian stimulation protocol on incidance 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 interferece of clomiphene citrate on etiology of LUF and so far few stydies have investigated incidence of LUF and relation with follicular size ,hormonal profile (luteal phase progesterone,FSH,LH)and endometial thickness in other ovarian stimulation regimens,this study is designed with purpose of evaluation and comparision 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 administred 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 untile one follicle reaches>> 18mm.Then HCG 10000IU IM is administred 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 βhcg.

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)

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+98 21888977614

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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 incidance of luteinized unruptured follicle syndrome in infertile women undergoing induction ovulation and intrauterine insemination

Public title

effect of ovarian stimulation drugs on incidance 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 malfprmation 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 stydy
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.Mansooreh 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
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Infertility fellowship assistant
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