Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison study between clomiphene citrate and letrozole on semen analysis in idiopathic oligospermic infertile men

Protocol summary

Summary

The main purpose:A comparison study between clomiphene citrate and letrozole on semen analysis in idiopathic oligospermic infertile men; Design study: Single-blind randomized clinical trial, treatment with medication, single-center; Study population: men; Inclusion criteria: Infertile men with sperm concentration, less than15 million per milliliter progressive motility, less than 32% total (progressive + non-progressive) motility,less than 40% , or morphologically normal forms,less than 4.0% ; Exclusion criteria for study: Infertile male with Varicocele, Abnormal FSH,LH,TSH,Testestrone and Prolactin, Abnormal liver or kidney function tests; Sample size: 80 people, two groups of 40 people; Interventions: A total of 80 infertile men (according to WHO criteria in 2010, without clinical varicocele and with normal hormonal assay) will randomly be all coated to clomiphene (clomide, Iran hormone, Tehran/Iran, 25 milligram daily) or Letrozol (Letrofam, Iran Hormone/ Tehran/Iran, 2.5 milligram daily) for 3 months. Semen Analysis will be assessed one week before and 3 months after last medications.(in one lab by one person); Intervention time: 3 months; The outcome of the study:Sperm concentrating, Sperm motility , Sperm morphology and semen volume according to the semen analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041721344N2**
Registration date: **2016-04-26, 1395/02/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-26, 1395/02/07

Registrant information

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Name of organization / entity
Semnan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Expected recruitment start date
2012-08-19, 1391/05/29
Expected recruitment end date
2012-11-20, 1391/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

A comparison study between clomiphene citrate and letrozole on semen analysis in idiopathic oligospermic infertile men

Public title

clomiphene and letrozole in idiopathic oligospermic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Infertile men with sperm concentration,

less than15 million per ml progressive motility, less than 32% total (progressive + non-progressive) motility,less than 40% , or morphologically normal forms,less than 4.0% ؛ exclusion criteria:Infertile male with Varicocele, Abnormal FSH and LH and TSH and Testestrone and Prolactin, Abnormal liver or kidney function tests.

Age
No age limit

Gender
Male

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Semnan University Of Medical Scienes &amp

Street address
Semnan University of Medical Sciences, BasijBoulevard

City
Semnan

Postal code
3519899951

Approval date
2012-08-14, 1391/05/24

Ethics committee reference number
175723/95

Health conditions studied

1

Description of health condition studied
Male infertility

ICD-10 code
N40-N51

ICD-10 code description
Diseases of male genital organs

Primary outcomes

1

Description
Sperm concentration

Timepoint
one week after last medication

Method of measurement
Semen analysis

Secondary outcomes

1

Description
Sperm motility

Timepoint
one week after last medication

Method of measurement
Semen analysis

2

Description
Sperm morphology

Timepoint
one week after last medication

Method of measurement
Semen analysis

3

Description
semen volume

Timepoint
one week after last medication

Method of measurement
Semen analysis

Intervention groups

1

Description
In first group clomiphene (clomide, Iran hormone, Tehran/Iran, 25 milligram daily) will be given for 3 months.

Category
Treatment - Drugs

2

Description
In second group Letrozol (Letrofam, Iran Hormone/ Tehran/Iran, 2.5 milligram daily) will be given for 3 months. Semen Analysis will be assessed one week after last medications.(in one lab by one person).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Hospital, Semnan

Full name of responsible person
Dr Azam Azargoon

Street address
Amiralmomenin Hospital,Imam Hossein Square, Semnan

City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Full name of responsible person
Dr Mohamad Reza Asgari

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Semnan University of Medical Sciences, Basij Boulevard

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Semnan

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor for Research and Technology, Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Dr Azam Azargoon

Position
Gynecologist / Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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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