

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

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

Protocol summary

2016-04-26, 1395/02/07

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 than 15 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, Testosterone 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

Registrant information

Name

Azam Azargoon

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

a-azargoon@semums.ac.ir

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 than 15 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 Testosterone 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 Sciences &

Street address

Semnan University of Medical Sciences,
Basij Boulevard

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

Street address

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**Street address**

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Person responsible for scientific inquiries

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Position

Gynecologist / Associate Professor

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Contact

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Full name of responsible person

Samaneh Lavvaf

Position

BS of Statistics/Expert Research Center Abnormal
Uterine Bleeding

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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