

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of HCG and clomiphene citrate on semen parameters in men with severe Oligoasthenospermia

Protocol summary

Study aim

The comparison of the effect of HCG and clomiphene citrate on semen parameters in men with severe Oligoasthenospermia

Design

By picking up a piece of paper that has been placed in a pack with equal numbers of 1 or 2, 90 patients will be divided into two groups of 1 or clomiphene citrate and 2 or HCG. The trial is parallel group randomized trial without blinding. Phase 3 of clinical trial.

Settings and conduct

All the infertile men who refer to Urology clinic of Imam Reza Hospital of Kermanshah University of Medical Sciences can participate in the study. Then according to inclusion and exclusion criteria 90 patients will be selected and randomly allocated into two groups. A base semen analysis will be obtained, then group one will be treated by 50 mg/PO/OD clomiphene citrate for 3 months and group 2 by 2500 U HCG/IM 3 times in week for 3 months. at the end of trial semen analysis will be obtained. Semen parameters between groups will be compared.

Participants/Inclusion and exclusion criteria

All the infertile men who refer to Urology clinic of Imam Reza Hospital of Kermanshah University of Medical Sciences can participate in the study. Inclusion criteria: Severe Oligoasthenospermia with less than 5 millions sperm Exclusion criteria: Definite etiology for Oligospermia, unwilling to participate

Intervention groups

group 1 or treatment by clomiphene citrate and 2 or treatment by HCG

Main outcome variables

Semen volume, Sperm count, the percent of abnormal sperms and motile sperms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180307038986N1**

Registration date: **2018-04-24, 1397/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

Registration date

2018-04-24, 1397/02/04

Registrant information

Name

Hossein Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6299

Email address

hossein.abdi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of HCG and clomiphene citrate on semen parameters in men with severe Oligoasthenospermia

Public title

HCG and clomiphene citrate and their effect on semen analysis parameters

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Severe Oligoasthenospermia Sperm count less than 5 million Male infertility

Exclusion criteria:

Male infertility due to a definite etiology Sever Oligoasthenospermia due to a definite etiology simultaneously consumption of the drugs that can affect male fertility (Testosterone, Steroids, Cimetidine, ...)

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

A 90 pieces of paper has been placed in a pack with fifty fifty numbers of 1 or 2. By picking up a piece of paper the patients will be allocated to the group 1 or clomiphene citrate and 2 or HCG.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Central Building of Kermanshah University of Medical Sciences, Shahid Beheshti Blvd., Kermanshah County.

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-01-17, 1396/10/27

Ethics committee reference number

lr.kums.rec.1396.571

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

Male Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

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

Semen volume, sperm count, the percent of abnormal sperms, the percent of motile sperms

Timepoint

Before the trial, 3 months after trial start

Method of measurement

Semen analysis

Secondary outcomes

empty

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

Intervention group: Group one will be treated by 50 mg/PO/OD clomiphene citrate for 3 months

Category

Treatment - Drugs

2**Description**

Intervention group: Group 2 will be treated by 2500 U HCG/IM 3 times in week for 3 months

Category

Treatment - Drugs

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

Urology clinic Imam Reza Hospital of Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hossein Abdi

Street address

Boostan clinic of Imam Reza Hospital of Kermanshah

University of Medical Sciences, Parastar Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hossein Abdi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hossein Abdi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

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Position

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Latest degree

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Urology

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Dr. Hossein Abdi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The gathered data and SPSS of the data and their analysis

When the data will become available and for how long

2019

To whom data/document is available

All the researchers who request to have our data and can be helpful for their studies

Under which criteria data/document could be used

Through requesting the data via calling or mailing to corresponding author

From where data/document is obtainable

Corresponding Author

What processes are involved for a request to access data/document

Evaluating the request, responding to it, if it is possible to do. It will take about 5 days.

Comments