

# 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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**Phone**

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**Email**

hossein.abdi@kums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Abdi

**Street address**

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

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**Email**

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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

**Street address**

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## Person responsible for scientific inquiries

**Contact**

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Kermanshah University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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## Person responsible for updating data

**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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**Email**

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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**