

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Investigating the effect of human menopausal gonadotropin and human chorionic gonadotropin treatment on testicular biopsy results in Klinefelter patients.

Protocol summary

Study aim

Investigating the effect of human menopausal gonadotropin and human chorionic gonadotropin treatment on testicular biopsy results in Klinefelter patients.

Design

This is a randomized clinical trial with a parallel design, which is nonblinded and with a control group. This study is randomized, phase 2-3 study will be conducted on at least 44 Klinefelter syndrome patients. A table of random numbers is used for randomization and the participants are assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted at the Bostan Clinic in Kermanshah, is a nonblinded one. The researcher and the participants have no role in the process of randomization and allocation of intervention and control groups. Medicines can only be identified through the serial number on the container.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Age between 18 and 65 years; Diagnosis of azoospermia based on semen analysis and urologist diagnosis; Married patients
Exclusion criteria: Any genetic disease other than Klinefelter that is associated with infertility; Presence of any concomitant disease that leads to infertility, such as varicocele; A history of infertility for any reason in the patient's wife; The patient's single testicle

Intervention groups

In the intervention group, HCG ampoules with a dose of 5000 units and HMG ampoules with a dose of 75 units are prescribed twice a week by intramuscular injection for 6 weeks. No medicine is prescribed in the control group.

Main outcome variables

Presence and absence of sperm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N207**

Registration date: **2023-08-20, 1402/05/29**

Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**

Update count: **0**

Registration date

2023-08-20, 1402/05/29

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of human menopausal gonadotropin and human chorionic gonadotropin treatment on testicular biopsy results in Klinefelter patients.

Public title

Investigating the effect of human menopausal gonadotropin and human chorionic gonadotropin treatment on testicular biopsy results

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent Age between 18 and 65 years
Diagnosis of azoospermia based on semen analysis and urologist diagnosis Married patients

Exclusion criteria:

Any genetic disease other than Klinefelter that is associated with infertility Presence of any concomitant disease that leads to infertility, such as varicocele A history of infertility for any reason in the patient's wife The patient's single testicle

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a simple random method. To hide the random allocation, the method of closed envelopes with random sequence (SNOSE) will be used, a number of envelopes, preparation and each of the created random sequences will be recorded on a card and the cards will be placed in the letter envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued, and it is placed inside the boxes in order. At the time of starting the registration of the participants, according to the order of entry of the eligible participants to the study, one of the letter envelopes will be opened and the assigned group of that participant will be revealed.

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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2023-03-12, 1401/12/21

Ethics committee reference number

IR.KUMS.MED.REC.1401.299

Health conditions studied

1

Description of health condition studied

Male Infertility

ICD-10 code

N46.1

ICD-10 code description

Oligospermia

Primary outcomes

1

Description

Presence and absence of sperm

Timepoint

The beginning of the study and the end of the study (6 weeks after the start of treatment)

Method of measurement

Sperm test

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, HCG ampoules with a dose of 5000 units and HMG ampoules with a dose of 75 units are prescribed twice a week by intramuscular injection

for 6 weeks.

Category

Treatment - Drugs

2

Description

No medicine is prescribed in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bostan Clinic

Full name of responsible person

Dr. Hossein Abdi

Street address

Bostan Clinic, Emam Reza Hospital, Parastar
Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

abdihosseini96@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Cyrus Jalili

Street address

Vice Chancellor for Research Affairs, Kermanshah
University of Medical Sciences, Building No.2, Shahid
Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

cjalili@kums.ac.ir

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. Behrouz Rostami

Position

Resident of kidney, urinary and genital tracts

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

Behrouzrostami1368@yahoo.com

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hossein Abdi

Position

Member of the academic staff of Kermanshah
University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

abdihosseini96@yahoo.com

Postal code

6715847141

Phone

+98 83 3427 6306

Email

Behrouzrostami1368@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Behrouz Rostami

Position

Resident assistant of kidney, urinary and genital tracts

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available