

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of hormonal therapy versus no treatment on testicular histopathology and fertility in patients with non-obstructive azoospermia: a before-after clinical trial

Protocol summary

Summary

Objectives: To assess the effect of hormonal therapy versus no treatment on testicular histopathology and fertility in patients with non-obstructive azoospermia. Design: a before-after clinical trial. Setting and conduct: The eligible patients with non-obstructive azoospermia who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: Male; non-obstructive azoospermia; normal sexual hormones. Exclusion criteria: Severe testicular atrophy; varicocele; chromosomal abnormality; sertoli cell syndrome; hypogonadism. Intervention group 1: Injection of HCG 5000 U intramuscularly once a week for 10 weeks. Intervention group 2: Injection of FSH 75 U intramuscularly twice a week for 10 weeks. Primary outcome: (a) sperm analysis 10 weeks after treatment through laboratory sampling; (b) histopathology of testis 10 weeks after treatment through biopsy. Randomization: This is a before after trial without randomization. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612069014N137**
Registration date: **2016-12-18, 1395/09/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-18, 1395/09/28

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hormonal therapy versus no treatment on testicular histopathology and fertility in patients with non-obstructive azoospermia: a before-after clinical trial

Public title

Effect of hormonal therapy versus no treatment on testicular histopathology and fertility in patients with non-obstructive azoospermia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male; non-obstructive azoospermia;

normal sexual hormones. Exclusion criteria: Severe testicular atrophy; varicocele; chromosomal abnormality; sertoli cell syndrome; hypogonadism.

Age
No age limit

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features
Randomization: This is a before after trial without randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.UMSHA.REC.1394.130

Health conditions studied

1

Description of health condition studied

non-obstructive azoospermia

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

sperm analysis

Timepoint

10 weeks after treatment

Method of measurement

through laboratory sampling

2

Description

histopathology of testis

Timepoint

10 weeks after treatment

Method of measurement

trough biopsy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Injection of HCG 5000 U intramuscularly once a week for 10 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Injection of FSH 75 U intramuscularly twice a week for 10 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Farid Tahmoorsi

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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**

Shahid Beheshti Hospital

Full name of responsible person

Dr Farid Tahmoorsi

Position

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Urologist

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Person responsible for updating data

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Associate Professor

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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