Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of HCG therapy on the amount of sperm extraction in men with non-obstructive azoospermia

Protocol summary

Study aim

Determining and comparing the average number of motile sperm in the semen sample before and after HCG therapy in the control and intervention groups؛ Determining and comparing the average number of motile sperm in TESE samples after HCG therapy in control and intervention groups؛ Determining and comparing the average LH level in intervention and control groups before and after HCG therapy؛ Determining and comparing the average FSH level in intervention and control groups before and after HCG therapy؛ Determining and comparing the average prolactin level in intervention and control groups before and after HCG therapy؛ Determining and comparing the average testosterone level in intervention and control groups before and after HCG therapy؛

Design

Clinical trial with a control group, with parallel groups, double-blind, simple randomized, phase 2 on 64 patients.

Settings and conduct

Ali Bin Abi Taleb Zahedan Hospital; injection of hccg to azoospermic patients; Blinding: The patient and the researcher are blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria: male patients with infertility caused by non-obstructive azoospermia at least twice Semen Analysis Exit criteria: 1- Male patients with obstructive azoospermia, - Male patients who received exogenous testosterone, 3-- Male patients who receive chemotherapy or radiotherapy at the time of study, 4- Male patients with unilateral or bilateral unpalpable testicles and 5- Male patients with increased serum prolactin. 6- Male patients with confirmed chromosomal abnormalities

Intervention groups

In patients who meet the study entry criteria, HCG will be prescribed as 5000 IU subcutaneous injection twice a week for 10 to 14 weeks. The control group will not receive an injection.

Main outcome variables

Help to improve infertility

General information

Reason for update

Acronym

hcg

IRCT registration information

IRCT registration number: **IRCT20240222061085N1**
Registration date: **2024-03-04, 1402/12/14**
Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**
Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name
Abdol-rahman Kalkali
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 915 285 7422
Email address
abdikalkali@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-19, 1402/12/29

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of HCG therapy on the amount of sperm extraction in men with non-obstructive azoospermia

Public title

The effect of HCG therapy on the amount of sperm extraction in men with non-obstructive azoospermia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male patients with infertility caused by non-obstructive azoospermia at least twice Semen Analysis

Exclusion criteria:

They received exogenous testosterone receive chemotherapy or radiotherapy at the time of study Unilateral or bilateral non-palpable testicles and Increased serum prolactin. Confirmed chromosomal abnormalities

Age

From **20 years** old to **60 years** old

Gender

Male

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

*Allocation concealment is done using 'coincidence sequence sealed opaque envelopes'. In this way, the random sequence is determined first, then the sequences are recorded on a card and the cards are placed in the envelopes in order. The outer surface of the envelopes is numbered and placed in the box in order. Participants will choose an envelope in order of entry and the intervention group will be determined.

Blinding (investigator's opinion)

Double blinded

Blinding description

*Blinding: it is double-blind, the patient is not aware of the type of intervention performed, and on the other hand, the doctor evaluating the outcome of the study is also not aware of the type of treatment used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Persian Gulf Blvd., Dr. Hasabi Square, Zahedan Medical Sciences Campus

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2024-01-29, 1402/11/09

Ethics committee reference number

IR.ZAUMS.REC.1402.419

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

The rate of sperm extraction in men with non-obstructive azoospermia

Timepoint

3 months after receiving hcg

Method of measurement

Sperm analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients who meet the study entry criteria, HCG will be prescribed as 5000 IU subcutaneous injection twice a week for 10 to 14 weeks. After the end of the HCG therapy period, sperm analysis will be taken

from the patient's semen and the number of motile sperm as well as the serum level of LH, FSH, testosterone and prolactin will be checked and recorded. If in the Semen sample after HCG therapy, the patient still has azoospermia, he will be subjected to TESE for sperm extraction. In all stages of testing and sampling, patient information will remain confidential and ethical codes of research on human samples will be observed.

Category

Treatment - Drugs

2

Description

Control group: This group includes patients who are azoospermic and did not consent to receiving the HCG drug. This group will not receive drug treatment and will be followed periodically like the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali bin Abi Talib (AS) Zahedan Hospital

Full name of responsible person

AbdolRahman Kalkali

Street address

Persian Gulf Boulevard, Ali Bin Abi Taleb (AS) Hospital

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

Abdikalkali@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Zahedan University of Medical Sciences

Street address

Fars Gulf Blvd., Dr. Hasabi Flat, Zahedan Medical Sciences Campus

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3337 2151

Email

abdikalkali@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

AbdolRahman Kalkali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Zibashar, Pirozi 4

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817911905

Phone

+98 915 285 7422

Email

Abdikalkali@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Abdol-rahman Kalkali

Position

Urology resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Baharan complex, Payambar ahzam, Zibashar

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817911905

Phone

+98 915 285 7422

Fax

Email

abdikalkali@Gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Abdol-Rahman Kalkali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Zibashar, Pirozi 4

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817911905

Phone

+98 915 285 7422

Email

Abdikalkali@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data from infertile people receiving hcg

When the data will become available and for how long

The access period starts 1 month after the results are published

To whom data/document is available

Scientific researchers

Under which criteria data/document could be used

The use of data in pregnancy research is not prohibited.

From where data/document is obtainable

Ali Bin Abi Talib (AS) Hospital - Research Center - Dr. Abdol-Rahman Kalkali

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

After registering the research title in the field of fertility, it will be possible to access the data.

Comments