

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

effect of varicocelelectomy and/or mast cells stabilizer on sperm DNA fragmentation in infertile patients with varicocele

Protocol summary

Study aim

Evaluation of the stabilizing effect of mast cells (with and without varicocelelectomy) on sperm DNA fracture and spermogram in infertile men and its comparison with varicocelelectomy alone

Design

A clinical trial with a control group, with parallel, randomized groups, will be performed on 255 patients. There is a control group and two intervention groups. Participants enter each group at random after informed consent, and the DNA Fragmentation Index (DFI) will be measured before and after three months and compared between the groups.

Settings and conduct

At Ghaem Hospital and Milad Infertility Center, eligible patients underwent two DNA Fragmentation index (DFI) tests before the course and three months after the start of treatment and were monitored, and the results were analyzed. The analyst will be unaware of the intervention and control groups. Due to the differences in different treatments (presence / absence of surgery), it is not possible to blind patients and physicians (evaluators).

Participants/Inclusion and exclusion criteria

Entry conditions: Men of childbearing age who complain of (male) infertility and have varicocele and informed consent. Non-entry conditions: allergic reaction or drug complication, leukocytospermia, azoospermia, diabetics

Intervention groups

1. Those who undergo varicocelelectomy microsurgery. 2. Those who are treated with 1 mg of oral ketotifen twice daily for three months. 3. Those who have undergone microsurgical varicocelelectomy and are treated with 1 mg twice daily of ketotifen for three months.

Main outcome variables

DNA Fragmentation index (DFI) quantitatively in the form of chromosomal failure rate and spermogram quantitatively in the form of semen analysis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211217053436N1**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **retrospective**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

Registration date

2022-01-27, 1400/11/07

Registrant information

Name

Alireza akhavan rezayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3894 2203

Email address

sheikhzadehmm911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-29, 1399/06/08

Expected recruitment end date

2021-05-29, 1400/03/08

Actual recruitment start date

2020-08-29, 1399/06/08

Actual recruitment end date

2021-11-29, 1400/09/08

Trial completion date

2021-11-29, 1400/09/08

Scientific title

effect of varicocelelectomy and/or mast cells stabilizer on sperm DNA fragmentation in infertile patients with varicocele

Public title

The effect of varicocelelectomy and mast cell stabilizer on sperm DNA fragmentation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile men due to varicocele (in reproductive age)

Informed consent

Exclusion criteria:

Allergic reaction to drug Drug complication

Leukocytospermia Azoospermia Diabetics

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **123**

Actual sample size reached: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done using Excel software or dedicated randomization sites. Each group is assigned a code (for example, A, B, C). We write the codes in the order of the specified order on separate sheets. We put each sheet in a separate concealment envelope and close the lid. After referring each qualified patient and obtaining informed consent from him, an envelope is opened for the patient and according to the code written in it (A, B, C) the patient is placed in one of the three study groups.

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 mashhad university of medical sciences

Street address

Qaem hospital, urology department, Ahmad Abad

street

City

Mashhad

Province

Razavi Khorasan

Postal code

9178914833

Approval date

2021-01-26, 1399/11/07

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.689

Health conditions studied

1

Description of health condition studied

Infertility caused by varicocele

ICD-10 code

I86.1

ICD-10 code description

Scrotal varices

Primary outcomes

1

Description

Sperm DNA fragmentation

Timepoint

Before intervention and 3 months after intervention

Method of measurement

DNA Fragmentation Index percentage.

2

Description

Semen Analysis

Timepoint

Before intervention and 3 months after intervention

Method of measurement

Semen Analysis

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the control group, individuals undergo only varicocelelectomy microsurgery and the outcome is evaluated after 3 months. (Surgery only)

Category

Treatment - Surgery

2

Description

First Intervention group: Those who are treated with 1

mg of oral ketotifen tablet (Which were usually the product of various domestic pharmaceutical companies and no specific brand was considered.) twice a day for three months. (Pharmaceutical only)

Category

Treatment - Drugs

3

Description

Second Intervention group: Those who have undergone varicocele micro surgery and are still treated daily with 1 mg of ketotifen tablet (Which were usually the product of various domestic pharmaceutical companies and no specific brand was considered.) for three months. (Both surgery and medication)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Alireza Akhavan Aezayat

Street address

Ahmad Abad st.

City

Mashhad

Province

Razavi Khorasan

Postal code

9178914833

Phone

+98 51 3843 2256

Email

akhavanra@mums.ac.ir

2

Recruitment center

Name of recruitment center

Milad Infertility Research and Treatment Center

Full name of responsible person

Alireza Akhavan Rezayat

Street address

Akhond Khorasani 32 st.

City

Mashhad

Province

Razavi Khorasan

Postal code

9178914833

Phone

+98 51 3853 4021

Email

akhavanra@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Akhavan Rezayat

Street address

University Compound

City

Mashhad

Province

Razavi Khorasan

Postal code

9178914833

Phone

+98 51 3843 2256

Email

akhavanra@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Akhavan Rezayat

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

Ahmad Abad st.

City

Mashhad

Province

Razavi Khorasan

Postal code

9178914833

Phone

+98 51 3843 2256

Email

akhavanra@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Akhavan Rezayat

Position

Associate Professor

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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