

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Evaluation of the effect of new method of varicocele surgery (gubernectomy and) on fertility based on DNA fragmentation index

#### Protocol summary

##### Study aim

Identification of the causes leading to non-response to surgical treatment in patients suffering from varicocele and infertility and the invention of new techniques to improve surgical outcomes

##### Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, on 110 patients. Toss and coin was used for randomization.

##### Settings and conduct

Study is done on infertile people referred to the 501 hospital who have second and third degree varicocele and have impaired Deoxyribonucleic acid Fragmentation Index. The first group of patients undergo standard surgery without the help of a microscope, for patients of the second group, in addition to standard surgery, gubernaculum closure is performed

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: infertility, second and third degree varicocele, having DFI impaired sperm fluid analysis test  
Exclusion criteria: normal fertility, history of undescended testis, history of testicular torsion, having first-degree varicocele, no DFI abnormality in the semen analysis

##### Intervention groups

The first group of patients undergo standard surgery without the help of a microscope, for patients of the second group, in addition to standard surgery, gubernaculum closure is performed

##### Main outcome variables

Evaluation of the effect of different varicocele surgery techniques on the improvement of Deoxyribonucleic acid Fragmentation Index and fertility

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200122046220N2**

Registration date: **2021-04-04, 1400/01/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-04, 1400/01/15**

Update count: **0**

##### Registration date

2021-04-04, 1400/01/15

##### Registrant information

###### Name

arash karimi baba ahmadi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6693 8257

###### Email address

arashkarimi86@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2021-05-22, 1400/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of new method of varicocele surgery (gubernectomy and) on fertility based on DNA fragmentation index

##### Public title

Evaluation of varicocele surgery on deoxyribonucleic acid fragmentation index

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Infertile people with second and third degree varicocele  
Impaired Deoxyribonucleic acid fragmentation index

#### **Exclusion criteria:**

History of orchitis or testicular cancer Azoospermia  
History of inguinal or scrotal surgery Systemic inflammatory disease History of testicular trauma,

### **Age**

From **18 years** old to **50 years** old

### **Gender**

Male

### **Phase**

N/A

### **Groups that have been masked**

- Participant

### **Sample size**

Target sample size: **80**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Permuted block randomization method was used to create a random sequence. We considered the block size to be 4 so that in each block 2 patients were operated by conventional method and two patients by conventional method + gubernaculectomy. We entered information about the block size and sample size into the sealed envelope website to specify the desired sequence in each block. In this way, 20 blocks of size 4 were identified to randomize the sample size of 80. With this method, we were able to divide patients into two groups in a balanced and unpredictable way. Also to hide random allocation, custom codes created by the same website were used for each person entered into the study.

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

Participants do not know which surgical technique they undergo. Patients are not conscious during surgery. After surgery it is not possible for the patient to determine the type of technique due to the type of skin incision etc.

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

## **1**

### **Ethics committee**

#### **Name of ethics committee**

Ethics committee of AJA University of Medical Sciences

#### **Street address**

Unit 2, No. 9 Omrani Alley, Golshan intersection, Azarbayjan Ave.

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1315793518

### **Approval date**

2021-01-06, 1399/10/17

### **Ethics committee reference number**

IR.AJAUMS.REC.1399.201

## **Health conditions studied**

## **1**

### **Description of health condition studied**

Infertility associated with varicocele and impaired DFI

### **ICD-10 code**

### **ICD-10 code description**

## **Primary outcomes**

## **1**

### **Description**

Percentage of fertility and DFI improvement after surgery

### **Timepoint**

DFI measurement before and three months after surgery

### **Method of measurement**

Percentage of sperm with defective chromosomes to total sperms

## **Secondary outcomes**

empty

## **Intervention groups**

## **1**

### **Description**

Control group: People over the age of 18 with varicocele and infertility who have impaired Deoxyribonucleic acid Fragmentation Index in semen analysis (DFI > 30%) undergoing varicocele surgery in a standard approach (Closing the spermatic vessels of the cord without the help of a microscope in the inguinal canal)

### **Category**

Treatment - Surgery

## **2**

### **Description**

Intervention group: People over the age of 18 with varicocele and infertility who have impaired Deoxyribonucleic acid Fragmentation Index (DFI > 30%) in semen analysis undergoing varicocele surgery in a standard way plus gubernaculectomy

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Aja Hospital 501

**Full name of responsible person**

Arash Karimi Baba Ahmadi

**Street address**

Unit 2, No. 9 Omrani Alley, Golshan intersection, Azarbayjan Ave.

**City**

Tehran

**Province**

Tehran

**Postal code**

1318834651

**Phone**

+98 21 6693 8257

**Email**

arashkarimi86@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Arash Karimi Baba Ahmadi

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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**

Artesh 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**

Artesh University of Medical Sciences

**Full name of responsible person**

Arash Karimi Baba Ahmadi

**Position**

Non-Academic Specialist Physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Arash Karimi

**Position**

Non-Academic Specialist Physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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**Person responsible for updating data****Contact****Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

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**Position**

Non-Academic Specialist Physician

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data is potentially shareable after unidentified individuals

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

There are no restrictions

**From where data/document is obtainable**

Arash Karimi arashkarimi1510@yahoo.com

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

Access to data is done by sending an e-mail to the previous address

**Comments**