

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Comparison of the effect of the various anesthesia following testicular sperm extraction (TESE) on sperm parameters in men with azoospermia undergoing ICSI

#### Protocol summary

##### Summary

The aim of this study is to evaluate the efficacy the various anesthesia in extraction a sufficient quality of sperm for men with Azoospermia undergoing ICSI. A single blind randomized clinical trial is done on Azoospermic men with very low sperm production within the testis in Infertility and Reproductive Health Research Center located in Babol (North of Iran). 100 Azoospermic men according inclusion criteria (age 20-50 years with Azoospermic ...) and exclusion criteria (men with a history of particular medicine to induce or suppress spermatogenesis...) randomly assign to two groups. In one group (control) using general anesthesia and the other group using (case) local anesthesia is done testicular sperm extraction. The concentration, motility and morphology of the spermatozoa present in each sample are evaluate immediately after processing, as well as 1 and 2 hours following processing. The values compared each other within and between both groups. First outcome is to improve of sperm parameters and second outcome is the side effect of drugs.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201505071760N39**

Registration date: **2015-05-16, 1394/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-16, 1394/02/26

##### Registrant information

Name

Nargess Gholizadeh Pasha

##### Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3236 2282

##### Email address

zahra@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

##### Expected recruitment start date

2011-08-23, 1390/06/01

##### Expected recruitment end date

2013-01-20, 1391/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of the various anesthesia following testicular sperm extraction (TESE) on sperm parameters in men with azoospermia undergoing ICSI

##### Public title

Comparison of the effect of the various anesthesia following testicular sperm extraction (TESE) on sperm parameters in men with azoospermia undergoing ICSI

##### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Age 20-50 years; Azoospermic men; Body mass index between 19 and 28; Exclusion criteria: Men with a history of particular medicine to induce or suppress Spermatogenesis; High temperature; Radiotherapy; Lower abdomen surgery; Smoking; Alcohol; Failure to hypogonadism in the last three months

## Age

From **20 years** old to **50 years** old

## Gender

Male

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

This is a test done by the blind.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical sciences

##### Street address

Babol University of Medical Sciences, Ganjafroz Avenu

##### City

Babol

##### Postal code

#### Approval date

2011-07-23, 1390/05/01

#### Ethics committee reference number

4268

## Health conditions studied

### 1

#### Description of health condition studied

Azoospermia

#### ICD-10 code

N46

## ICD-10 code description

Male infertility

## Primary outcomes

### 1

#### Description

Improve sperm

#### Timepoint

One hour, two hour after testicular sperm extraction (TESE)

#### Method of measurement

Laboratory

## Secondary outcomes

### 1

#### Description

Side effects of drugs

#### Timepoint

During drug use

#### Method of measurement

Clinical

## Intervention groups

### 1

#### Description

Intervention Groups: Local anesthesia with Lidocaine (10 cc 2% plain Lidocaine (Sina Daru Ltd, Iran)

#### Category

Treatment - Drugs

### 2

#### Description

Controls Groups: General anesthesia

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatemeh-Zahra Fertility & infertility Medical Center

##### Full name of responsible person

Masoomeh Golsorkgtabar Amiri

##### Street address

Fatemeh-Zahra Medical Center-Fatemeh-zahra Infertility & Reproductive Health ResearchCenter , Amol, Babol, Old Road, After Mohammad Hassan Khan Bridg

##### City

Babol

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research and Technology, Babol  
University of Medical Sciences

**Full name of responsible person**

Dr. Ali Bijani

**Street address**

Babol University of Medical Sciences, Ganjafroz  
Avenue

**City**

Babol

**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 and Technology, Babol  
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**

Fatemehzahra Infertility & Reproductive Health  
Research Center

**Full name of responsible person**

Dr. Molood Aghajani Delavar

**Position**

PhD in Women's Health

**Other areas of specialty/work****Street address**

Fatemehzahra Infertility & Reproductive Health  
Research Center, After Mohammad Hassan Khan  
Bridge, old Road Amol

**City**

Babol

**Postal code****Phone**

+98 11 3227 4881

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moloodaghajani@yahoo.com

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Fatemehzahra Infertility & Reproductive Health  
Research Center

**Full name of responsible person**

Dr. Hamid Shafi

**Position**

Urologist

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Nargess Gholizadeh Pasha

**Position**

MSc

**Other areas of specialty/work****Street address**

Babol University of Medical sciences, Ganjafroz  
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**Web page address**

## 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*