

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Randomised clinical trial for assessment of effects of local intraoperative mitomycin during vasovasostomy on sperm analysis results

#### Protocol summary

##### Summary

**Abstract:** Objective: To introduce a method for increasing of vasovasostomy success rate. Study plan: Randomized, single blind, controlled, without placebo, single centered. Population: Males who will undergo vasectomy and will refer to Shohada-ye Tajrish medical center. Inclusion criteria: Males who will undergo vasectomy. Exclusion criteria: History of urethral or bladder neck surgery; History of previous vasovasostomy; History of scrotal region radiotherapy or chemotherapy; Age of partner out of fertility range. Target sample size: 40 Interventions: Intervention group: vasovasostomy with local intraoperative mitomycin 0.2 mg/dl for 5 minutes. Control group: standard vasovasostomy without local intraoperative mitomycin and without placebo. Duration of intervention: 6 months Outcomes of study: Presence of sperm in semen; Sperm count; Sperm motility rate; Normal morphology rate in sperms.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015092324166N1**  
Registration date: **2016-12-12, 1395/09/22**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-12, 1395/09/22

##### Registrant information

###### Name

Hamidreza Qashqai

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 230 7789

###### Email address

qashqae@sbmu.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

###### Expected recruitment start date

2016-01-21, 1394/11/01

###### Expected recruitment end date

2016-12-20, 1395/09/30

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Randomised clinical trial for assessment of effects of local intraoperative mitomycin during vasovasostomy on sperm analysis results

###### Public title

Comparison of vasovasostomy outcomes with and without local intraoperative mitomycin

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Males who undergo vasectomy.

Exclusion criteria: History of urethral or bladder neck surgery; History of previous vasovasostomy; History of scrotal region radiotherapy or chemotherapy; Age of partner out of fertility range.

###### Age

No age limit

###### Gender

Male

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization will be performed by closed pockets method.

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti university of medical sciences

**Street address**

Shahid Beheshti university of medical sciences, Aarabi Av., Yaman st., Velenjak

**City**

Tehran

**Postal code**

**Approval date**

2016-06-21, 1395/04/01

**Ethics committee reference number**

IR.SBMU.MSP.REC.1395.100

**Health conditions studied**

1

**Description of health condition studied**

Male Infertility

**ICD-10 code**

N46

**ICD-10 code description**

Male infertility Incl.: Azoospermia NOS Oligospermia NOS

**Primary outcomes**

1

**Description**

Presence of sperm in semen

**Timepoint**

Six months after surgical procedure

**Method of measurement**

Semen analysis

2

**Description**

Sperm count

**Timepoint**

Six months after surgical procedure

**Method of measurement**

Semen analysis

3

**Description**

Sperm motility rate

**Timepoint**

Six months after surgical procedure

**Method of measurement**

Semen analysis

4

**Description**

Normal morphology rate in sperms

**Timepoint**

Six months after surgical procedure

**Method of measurement**

Semen analysis

**Secondary outcomes**

1

**Description**

Hematoma in operation site

**Timepoint**

1 month after procedure, 3 months after procedure and 6 months after procedure

**Method of measurement**

Physical examination

2

**Description**

Inflammatory reaction in surgical site

**Timepoint**

1 month after procedure, 3 months after procedure and 6 months after procedure

**Method of measurement**

Physical examination

3

**Description**

Tissue necrosis in surgical site

**Timepoint**

1 month after procedure, 3 months after procedure and 6 months after procedure

**Method of measurement**

Physical examination

#### 4

##### **Description**

Failure of operation

##### **Timepoint**

1 month after procedure, 3 months after procedure and 6 months after procedure

##### **Method of measurement**

Sperm analysis

#### **Intervention groups**

#### 1

##### **Description**

Inntervention group: vasovasostomy with local intraoperative mitomycin 0.2 mg/dl for 5 minutes

##### **Category**

Treatment - Surgery

#### 2

##### **Description**

Control group: standard vasovasostomy without local intraoperative mitomycin and without placebo

##### **Category**

Treatment - Surgery

#### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Shohada-e Tajrish Medical Center

###### **Full name of responsible person**

Dr. Farzad Allameh

###### **Street address**

Qods sq., Tajrish

###### **City**

Tehran

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

###### **Full name of responsible person**

Dr. Afshin Zarghi

###### **Street address**

Shahid Beheshti University of Medical Sciences, Aarabi Av., Yaman St., Velenjak,

###### **City**

Tehran

##### **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 of Shahid Beheshti 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 University of Medical Sciences, Urology department

###### **Full name of responsible person**

Dr. Hamidreza Qashqai

###### **Position**

Urology Resident

###### **Other areas of specialty/work**

###### **Street address**

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#### **Person responsible for scientific inquiries**

##### **Contact**

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## Person responsible for updating data

### Contact

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**Position**

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

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**Postal code**

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**Fax****Email**

qashqae@sbmu.ac.ir; qashqae@gmail.com

**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*