

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The efficacy of one of the Iranian Traditional Remedy(lobub morakab) in spermogram parameter in Idiopathic Male Infertility in Imam Khomeyni hospital

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the efficacy of Iranian herbal remedy on spermogram parameter in men with idiopathic infertility.

##### Design

This study is a clinical trial without a control group and placebo, in the form of before\_after analysis.

##### Settings and conduct

The infertile patients were referred to the Persian medicine infertility clinics in Imam Khomeini Hospital Complex with idiopathic oligo-astheno-teratozoospermia according to inclusion and exclusion criteria intake drug dose.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Men 20-45 years; 2. infertility for at least one year; 3. oligo-astheno-teratozoospermia unexplained according to WHO. Exclusion criteria: 1. The history of intake of chemotherapy, corticosteroid, anticoagulation, testosterone, and antiandrogen; 2. The incidence of severe cases of oligospermia; 3. infections, genital anatomical abnormalities, chromosomal abnormalities, history of surgery on the genital tract, and exposure to toxins; 4. Alcohol or drug abuse; 5. systemic diseases.

##### Intervention groups

The therapeutic dose is 5 g from remedy BID for 3 months, and after 3 months samples tested and new spermogram be analyzed, and the results will be compared.

##### Main outcome variables

Improving sperm volume or concentration or sperm motility or normal morphology of sperm is important.

#### General information

##### Reason for update

Making minor changes in some parts after the end of the

trial

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100624377N1**

Registration date: **2015-11-06, 1394/08/15**

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

Last update: **2023-02-14, 1401/11/25**

Update count: **2**

##### Registration date

2015-11-06, 1394/08/15

##### Registrant information

###### Name

Somaye Mahroozade

###### Name of organization / entity

Iranian Traditional Medicine school, Tehran University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2264 1913

###### Email address

mahrouzs891@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences, Iranian Traditional Medicine fac

##### Expected recruitment start date

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-02-04, 1394/11/15

##### Actual recruitment start date

2015-09-23, 1394/07/01

##### Actual recruitment end date

2016-02-04, 1394/11/15

**Trial completion date**

2016-05-21, 1395/03/01

**Scientific title**

The efficacy of one of the Iranian Traditional Remedy(lobub morakab) in spermogram parameter in Idiopathic Male Infertility in Imam Khomeyni hospital

**Public title**

The efficacy of one of the Iranian Traditional Remedy on spermogram in infertile men

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men 20-45 years Infertility for at least one year Unexplained Oligo-astheno-teratozoospermia according to WHO criteria: Sperm concentrations below 20 million per milliliter; 5. Motile sperm less than 50%; 6. The normal morphology less than 30%

**Exclusion criteria:**

History of taking chemotherapy, Corticosteroid, Anticoagulation, Testosterone, Antiandrogen The incidence of severe cases of oligospermia (sperm concentration less than one million per milliliter) Infections, genital anatomical abnormalities, chromosomal abnormalities, history of surgery on the genital tract, exposure to toxins Alcohol or drug abuse Systemic diseases (cancer, thyroid disease, liver and gall bladder diseases, renal failure, etc.) The reluctance of patients to continue Make any side effects from medication

**Age**

From **20 years** old to **45 years** old

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **43**

Actual sample size reached: **43**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The ethics committee of Tehran University of Medical Sciences

**Street address**

Tehran University of Medical Sciences,Qods St, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2015-10-11, 1394/07/19

**Ethics committee reference number**

IR.TUMS.REC.1394.847

**Health conditions studied****1****Description of health condition studied**

Infertility

**ICD-10 code**

N46

**ICD-10 code description**

Diseases of male genital organs, Male infertility,

**Primary outcomes****1****Description**

Semen volume

**Timepoint**

At the beginning of the trial, 3 months after end of the drug

**Method of measurement**

Semen analysis

**2****Description**

Sperm count

**Timepoint**

At the beginning of the trial, 3 months after end of the drug

**Method of measurement**

Sperm analysis

**3****Description**

Sperm motility

**Timepoint**

At the beginning of the trial, 3 months after end of the drug

**Method of measurement**

Semen analysis

## 4

### Description

Normal morphology

### Timepoint

At the beginning of the trial, 3months after end of the dru

### Method of measurement

Semen analysis

## Secondary outcomes

### 1

#### Description

Fertility

#### Timepoint

After treatment

#### Method of measurement

Partner pregnancy

### 2

#### Description

Side effects such as itching, etc.

#### Timepoint

During the intervention

#### Method of measurement

Patient report

## Intervention groups

### 1

#### Description

Remedy recommended 5 g, twice a day with milk for 3 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini hospital

##### Full name of responsible person

Somaye Mahroozade

##### Street address

Imam Khomeini hospital, Keshavarz Blvd.

##### City

Tehran

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##### Phone

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##### Email

Imamhospital@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Vice chancellor for research, Tehran University of Medical

##### Street address

Tehran university of Medical Science, Qods St, Keshavarz Blvd

##### City

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##### Postal code

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##### Email

stat@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

School of Persian Medicine, Iran University of Medical Sciences

##### Full name of responsible person

Somaye Mahroozade

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Traditional Medicine

##### Street address

School of Persian Medicine, Iran University of Medical Sciences, No. 847, Vahdat Eslami ST.

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Medical Faculty of Tehran University of Medical Sciences  
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Dr. Farnaz Sohrabvand  
**Position**  
Professor  
**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Other areas of specialty/work**  
Traditional Medicine  
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**Web page address**

## 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

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

### 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