

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

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Iran (Islamic Republic of)

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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

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Tehran University of Medical Sciences, Qods St, Keshavarz Blvd

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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, 3 months after end of the drug

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

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

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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

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