

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Double Blind Randomized placebo Controlled Clinical trial to compare the effect of dietary regimen with and without Lobub (A complex drug) for treatment of male subfertility with cold temperament according to Iranian Traditional Medicine

Protocol summary

Summary

Objective: Double blind randomized placebo controlled clinical trial to compare the effect of dietary regimen with and without Lobub (a complex drug) for treatment of male subfertility. Method: The patients with male factor subfertility will be randomized by block randomization to two groups; one group diet and placebo and the other diet and Lobub. The medication will be prepared by pharmaceuticals university of medical sciences. After history taking and physical examination and signing written consent forms, questionnaires on functional ejaculation parameters will be completed. All of the patients will receive dietary advices. (Semen analysis before medication will be performed by andrology laboratory of infertility clinic. After 2 and 3 months semen analysis and questionnaire completion will be repeated and the results will be compared) All experiments will be done in a center. (mother and child hospital infertility lab) TO avoid potential errors .all patients diet on the base of traditions medicine will be modified . And by block randomization method , to the first group lobub and to the second group placebo (made by traditional medicine, Shiraz University of Medical Sciences) will be administered . At the end of study the number, motility and normal sperm formation and fertility and performance indicators erection in the two groups will be measured. Inclusion criteria: All infertile men with body mass index less than 30, who have not dyspepsia and sinusitis, those who have not burning sensation during ejaculation and yellow semen (possibility of warm dystemperament) Exclusion criteria: Not willing to continue medication, sensitivity to the drug and complications. Primary outcome measures: Sperm morphology, motility and count Secondary outcome measure: functional ejaculation criteria In the intervention group: drug therapy (Lobub 5gr/day for 3

months). In the Control group: placebo, 5 grams per day for three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508036541N8**

Registration date: **2016-01-01, 1394/10/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-01, 1394/10/11

Registrant information

Name

Bahia Namavar Jahromi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 2365

Email address

namavarb@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research ,Shiraz University of Medical Sciences.

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double Blind Randomized placebo Controlled Clinical trial to compare the effect of dietary regimen with and without Lobub (A complex drug) for treatment of male subfertility with cold temperament according to Iranian Traditional Medicine

Public title

Comparing the effect of dietary regimen with and without Lobub (a complex drug) for treatment of male subfertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Subfertile men with BMI<30, who have not dyspepsia and sinusitis, those who have not burning sensation during ejaculation and yellow semen (possibility of warm dystemperament) without a documented standard medical treatment in the literature. Exclusion criteria: Not willing to continue medication, sensitivity to the drug and complications

Age

From **20 years** old to **60 years** old

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)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, patients will receive placebo or drug in accordance with block randomization list. Neither the patients nor the researchers are not aware of each subject receive what intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of medical Sciences

Street address

Shiraz University of Medical Sciences,Zand Street, Shiraz, Iran

City

Shiraz

Postal code

Approval date

2015-06-27, 1394/04/06

Ethics committee reference number

IR.SUMS.REC.1394.56

Health conditions studied

1

Description of health condition studied

Male Infertility

ICD-10 code

N 46

ICD-10 code description

Male Infertility

Primary outcomes

1

Description

Sperm morphology, motility and count

Timepoint

Before and 2, and 3 months after intervention

Method of measurement

By semen analysis using 2010 WHO criteria

Secondary outcomes

1

Description

Erectile function questionnaire

Timepoint

Before and 2, and 3 months after intervention

Method of measurement

Standard Questionnaire

Intervention groups

1

Description

Intervention group Drug therapy Lobub 5gr/day for 3 months

Category

Treatment - Drugs

2

Description

In the Control group, placebo to 5 grams per day for three months.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother & child hospital

Full name of responsible person

Dr. Amir Mohamad Jaladat

Street address

Ghadir Mother & child hospital- Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyd Basir Hashemi

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Shiraz University of Medical Sciences.Zand Street, Shiraz, Iran

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Shiraz

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 Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Amir Mohamad Jaladat

Position

Assistant professor of Traditional Persian Medicine

Other areas of specialty/work

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty