

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluate of effectiveness of Taroneh (traditional medicine product) on sperm parameters of infertile men and comparison with the drug pentoxifylline

Protocol summary

Summary

The aim of this study was to evaluate the effectiveness of Taroneh on sperm parameters of infertile men and comparison with the drug pentoxifylline. This study was a single-center, randomized, single-blind and phase III trial that will be performed on 80 infertile men with idiopathic oligoasthenoteratospermia. In this study patients were randomly using a tablet of divided in two groups: 40 people in the control group and 40 people in the intervention group. A spermogram will be done in the beginning of study. The intervention group was received 6 gr powder of sachet of Taroneh in two divided doses (3 gr every 12 hours) for 90 days. The control group was given daily 400 mg pentoxifylline tablet for 90 days. A blind assessment of spermogram will be done again 1 month after the end of treatment period. The evaluation of study is based on spermogram and the third party doesn't know anything about patients especially the drugs that patients have received so the evaluation is blind and this study is considered a single blind clinical trial. Inclusion criteria: Idiopathic Oligospermia; Idiopathic asthenospermia; Idiopathic teratospermia; Absence of azospermia; Non-consuming use of other drug for treatment of infertility, Exclusion criteria: the incidence of serious side effects. primary outcomes: Total number of sperms; Number of sperms in each ml of semen; Sperms motivation speed; Morphology Secondary outcomes: Semen volume; Viscosity; Reaction of upper respiratory tract to Taroneh.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111519965N1**

Registration date: **2016-02-19, 1394/11/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-19, 1394/11/30

Registrant information

Name

Mohammadreza Mirzaei Hargalan

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Tehran University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluate of effectiveness of Taroneh (traditional medicine product) on sperm parameters of infertile men and comparison with the drug pentoxifylline

Public title

Effect of Taroneh on treatment of male infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Idiopathic oligospermia; Idiopathic Asthenospermia; Idiopathic Teratospermia; Idiopathic Oligoasthenospermia; Idiopathic Oligoteratospermia; Idiopathic Oligoteratoasthenospermia; 18-35 Age; Patient's wife age 18-35; Absence of azoospermia; Non-consuming use of other drug for treatment of infertility during the study Exclusion criteria: lack of patient cooperation; the incidence of serious side effects, Age more than 35, Age of patient's spouse more than 35

Age

From **18 years** old to **35 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 done by random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, Keshavarz Ave, Tehran

City

Tehran

Postal code

Approval date

2015-05-10, 1394/02/20

Ethics committee reference number

IR.TUMS.REC.1394.146559

Health conditions studied

1

Description of health condition studied

male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Sperm count concentration

Timepoint

Before intervention and then four months after the start of intervention (one month after the end of intervention)

Method of measurement

Semen analysis

2

Description

Total sperm count

Timepoint

Before intervention and then four months after the start of intervention (one month after the end of intervention)

Method of measurement

Semen analysis

3

Description

Motility

Timepoint

Before intervention and then four months after the start of intervention (one month after the end of intervention)

Method of measurement

Semen analysis

4

Description

Morphology

Timepoint

Before intervention and then four months after the start of intervention (one month after the end of intervention)

Method of measurement

Semen analysis

Secondary outcomes

1

Description

Upper respiratory tract's reaction to Taroneh.

Timepoint

When the incidence of adverse drug reactions in patient

Method of measurement

According CTC (Common Toxicity Criteria)

2

Description

Volume

Timepoint

Before intervention and then four months after the start of intervention (one month after the end of intervention)

Method of measurement

Semen analysis

3

Description

Viscosity

Timepoint

Before intervention and then four months after the start of intervention (one month after the end of intervention)

Method of measurement

Semen analysis

Intervention groups

1

Description

Intervention Group: 3 gram powder of Taroneh in sachet, twice a day for 90 day Taroneh will purchase from south groves of Iran

Category

Treatment - Drugs

2

Description

Control Group: one tablet of Pentoxifylline (400mg) (Farabi pharmaceutical company) daily for 90 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Jasmine lover of women`s hospital

Full name of responsible person

Dr. Firozeh Akbari

Street address

The end of Ostad nejatollahi shomali street, karimkhan zand street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Roja Rahimi

Street address

College of Traditional Medicine of Tehran University of Medical, Behesht Street, Vahdat Eslami Street

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, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Mirzaei

Position

PhD Student of Traditional Medicine

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Full name of responsible person

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

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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