

# 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

Iran (Islamic Republic of)

###### Phone

+98 21 5596 0044

###### Email address

mirzaei-m@razi.tums.ac.ir

##### 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

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

##### **Street address**

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

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mirzaei-m@razi.tums.ac.ir

##### **Web page address**

## **Person responsible for scientific inquiries**

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Tehran University of Medical Sciences

**Full name of responsible person**

Mohammadreza Mirzaei

**Position**

PhD Student of Traditional Medicine

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

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

**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*