

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Study mixed herbal drug administration on semen antioxidants and testosterone level in male infertility; oligospermia

#### Protocol summary

##### Summary

The overall objective of the project to determine the health effects of mixtures of several plant on changes antioxidants in semen in men with oligospermia. This study is interventional. The samples number is 40 that herbal mixture with the shape of 700mg capsules produces and administrate it to the patients. Semen samples after a minimum of 2 and a maximum of 7 days to refrain from sexual contact in sterile plastic containers for liquid semen collection and analysis will be done in terms of antioxidants semen. The 700mg capsules dispose to the patients one-time daily. This 700mg capsules include equally proportion of Onions, ginger, basil, cinnamon, orange peel, yellow and red watermelon seed and carrot seed. Once the patients in the first day and the second time after 6 months of drug will gate sample. Semen samples after a minimum of 2 and a maximum of 7 days of abstinence from sexual contact is collected in sterile plastic containers And kits for measuring vitamin E Semen with method of (HPLC) High-performance liquid chromatography will be done. Other specific kits for measuring serum antioxidants measured by radio immunoassay political will. Inclusion criteria included patients with oligospermia without specific drugs using within the last six months without varicocele and without a history of systemic disease during the last six months and If there is a varicocele or systemic disease during the last six months or a particular drug within the last six months are excluded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012512146N3**

Registration date: **2014-07-24, 1393/05/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-07-24, 1393/05/02

##### Registrant information

###### Name

Laaya Farzadi

###### Name of organization / entity

Woman's Reproductive Health Research Center of Tabriz

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1553 9161

###### Email address

farzadl@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-01-19, 1391/10/30

##### Expected recruitment end date

2014-02-19, 1392/11/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study mixed herbal drug administration on semen antioxidants and testosterone level in male infertility; oligospermia

##### Public title

Effect of herbal drugs on the semen antioxidants

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Men with oligospermia enter the study if they sign informed consent and if they use some other drugs or if they have another diseases such az varicocele that effect on sperm analysis, they exclude from the study.

### **Age**

No age limit

### **Gender**

Male

### **Phase**

N/A

### **Groups that have been masked**

No information

### **Sample size**

Target sample size: 40

### **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**

Tabriz University of Medical Sciences

##### **Street address**

Tabriz University of Medical Sciences, Golbad street

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2014-06-26, 1393/04/05

#### **Ethics committee reference number**

9351

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

oligospermia

#### **ICD-10 code**

N46

#### **ICD-10 code description**

Male infertility

## **Primary outcomes**

### **1**

#### **Description**

Semen antioxidants level

#### **Timepoint**

Before the study and 6 months after study

#### **Method of measurement**

HPLC

### **2**

#### **Description**

serum testosterone level

#### **Timepoint**

Before the study and 6 months after study

#### **Method of measurement**

ng/dl

## **Secondary outcomes**

### **1**

#### **Description**

Sperm count

#### **Timepoint**

Before the study and 6 months after study

#### **Method of measurement**

Semen analysis

## **Intervention groups**

### **1**

#### **Description**

The samples number is 40 that herbal mixture with the shape of 700mg capsules produces and administrate it to the patients. Semen samples after a minimum of 2 and a maximum of 7 days to refrain from sexual contact in sterile plastic containers for liquid semen collection and analysis will be done in terms of antioxidants semen. The 700mg capsules dispose to the patients one-time daily.this 700mg capsules include equally proportio n of Onions, ginger, basil, cinnamon, orange peel, yellow and red watermelon seed and carrot seed . Once the patients in the first day and the second time after 6 months of drug will gate sample. Semen samples after a minimum of 2 and a maximum of 7 days of abstinence from sexual contact is collected in sterile plastic containers And kits for measuring vitamin E Semen with method of (HPLC) High-performance liquid chromatography will be done. Other specific kits for measuring serum antioxidants measured by radio immunoassay political will.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

1

### Recruitment center

**Name of recruitment center**

Infertility ward- Alzahra education and treatment center

**Full name of responsible person**

Hasti Alizadeh

**Street address**

Alzahra hospital- Artesh Jonoobi avenue - Baghshomal cross

**City**

Tabriz

### Sponsors / Funding sources

1

#### Sponsor

**Name of organization / entity**

Vice chancellor for Research, Tabriz University Of Medical Sciences

**Full name of responsible person**

Dr. Ali Reza Ostad Rahimi

**Street address**

Third Floor, Central Building of Number2, Golgasht Street specialized education assistant of tabriz university of medical science

**City**

Tabriz

**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, Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hasti Alizadeh

**Position**

MD, gynecology resident

**Other areas of specialty/work**

**Street address**

Golbad Street, Tabriz University Of Medical Sciences

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dr.hasti@ymail.com

**Web page address**

www.tbzmed.ac.ir

### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Laaya Farzadi

**Position**

Lecturer, gynecology specialist- infertility fellowship

**Other areas of specialty/work**

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### Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hasti Alizadeh

**Position**

MD, gynecology resident

**Other areas of specialty/work**

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**Email**

dr.hasti@ymail.com

**Web page address**

### 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*