

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison the effect of Iranian Traditional Medicine product (based on *Withania somnifera*) with Pentoxifylline on sperm parameters in the infertile men, triple-blind randomized Clinical trial

Protocol summary

Summary

Objective: The aim of this study is to compare the efficacy of Traditional Iranian Medicine product based on *Withania somnifera* with pentoxifylline on sperm parameters in the idiopathic infertile married men.

Design: This study is a triple blind controlled randomized Clinical trial. **Setting and conduct:** The 100 idiopathic infertile married men referring to Urology Clinic of Imam Reza Hospital with Infertility complaint and abnormality in count, motility and morphology of sperm analysis after confirming the urologist, containing inclusion/exclusion criteria and patients satisfaction will enter the study. **Inclusion criteria:** Men 18-45 years: infertility for at least one year: unexplained oligo-astheno-teratozoospermia according to WHO criteria: absence of systemic diseases. **Exclusion criteria:** Smoking or alcohol or drug abuse: intaking any other chemical drugs during the study. Patients were randomly divided into two groups of 50 men (*Withania somnifera* group and Pentoxifylline group). For all patients at first sperm analysis will be done. **Interventions:** In *Withania somnifera* receiving group, patients will receive 5 g of this product daily in the form of 5 capsules for 3 months. In pentoxifylline receiving group, patients will receive 800mg of pentoxifylline granules with placebo powder in the form of 5 capsules daily for 3 months. After 3 months, sperm analysis will be again tested for two groups. Main outcome of this study is improvement in count, motility, morphology of sperm and semen volume.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092224135N1**

Registration date: **2016-01-28, 1394/11/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-28, 1394/11/08

Registrant information

Name

Ramin Nasimi doost Azgomi

Name of organization / entity

School of Traditional Medicine, Tabriz University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 9529

Email address

nasimir@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-01-07, 1394/10/17

Expected recruitment end date

2016-09-07, 1395/06/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Iranian Traditional Medicine product (based on *Withania somnifera*) with Pentoxifylline on sperm parameters in the infertile men, triple-blind randomized Clinical trial

Public title

The efficacy of Withania somnifera on spermogram in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient satisfaction: Men 18-45 years: Infertility for at least one year with unexplained Oligo+/- astheno +/- teratozoospermia according to WHO criteria: Nonsmoking and nonaddiction to alcohol and drugs: No azospermia: No infections, No genital anatomical abnormalities: No risk of varicocele: No history of surgery on the genital tract: No Systemic diseases (cancer, thyroid diseases, liver and gall bladder diseases, renal failure, diabetes, uncontrolled hypertension, cerebral hemorrhage , retina bleeding, etc): No unilateral testicular atrophy: No history of taking chemotherapy, corticosteroid, anticoagulation, testosterone, antiandrogen. Exclusion criteria: Smoking or any kind of drug abuse during the study: Intaking any other chemical or herbal infertility drug during the study: Make any side effects from medication: The need for other interventions and surgery during the study: The reluctance of patients to continue.

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

In this study, randomization will be randomly done with fixed size blocks (Fixed size block randomization) and each block has a capacity of 50 people. Randomization list will be prepared by using stata13 software. In all phases of the study, the patient, the physician, the provider of drugs and collector of the data will be unaware of the medication type.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Postal code**Approval date**

2015-09-14, 1394/06/23

Ethics committee reference number

TBZMED.REC.1394.529

Health conditions studied**1****Description of health condition studied**

Male Infertility

ICD-10 code

N46

ICD-10 code description

Diseases of male genital organs, Male infertility

Primary outcomes**1****Description**

Sperm count

Timepoint

At the beginning of the trial, 90 days after the intervention

Method of measurement

Sperm analysis

2**Description**

Sperm motility

Timepoint

At the beginning of the trial, 90 days after the intervention

Method of measurement

Semen analysis

3**Description**

sperm morphology

Timepoint

At the beginning of the trial, 90 days after the intervention

Method of measurement

Semen analysis

4**Description**

Semen volume

Timepoint

At the beginning of the trial, 90 days after the intervention

Method of measurement

Semen analysis

Secondary outcomes

1

Description

To determine the potential adverse events resulting from treatment process in patients in the intervention groups

Timepoint

during the study

Method of measurement

questionnaire-Observation-reportage

Intervention groups

1

Description

In control group: receiving pentoxifylline, patients will receive 800mg of pentoxifylline granules +placebo powder daily in the form of 5 capsules in morning, noon, night for 3 months

Category

Treatment - Drugs

2

Description

In receiving traditional medicine product group(Withania somnifera), patients will receive 5 g of this product daily in the form of 5 capsules in morning,noon, night for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospita, Tabriz University of Medical Sciences

Full name of responsible person

Ramin Nasimi Doost Azgomi

Street address

Imam Reza Hospital, Golgasht street, Azadi street, Tabriz

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.Mohammad Reza Rashidi

Street address

No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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

School of Traditional Medicine, Tabriz University of Medical Sciences

Full name of responsible person

Ramin Nasimi Doost Azgomi

Position

Ph.D candidate of Traditional Medicine

Other areas of specialty/work

Street address

School of Traditional Medicine, Central Library of Tabriz University of Medical Sciences, Tabriz University, Golgasht street, Azadi street, Tabriz

City

Tabriz

Postal code

Phone

+98 41 3337 9529

Fax

+98 41 3337 9527

Email

Nasimir@tbzmed.ac.ir; Modir7060@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Imam Reza hospital, Tabriz University of Medical Sciences

Full name of responsible person

Dr.Afshar Zomorodi

Position

Urologist, kidney transplant fellowship, professor

Other areas of specialty/work

Street address

Urology ward, Imam Reza Hospital, Golgasht street,
Azadi street, Tabriz

City

Tabriz

Postal code

5166737618

Phone

+98 41 3335 7328

Fax

+98 41 3335 7328

Email

Dr_afshar@hotmail.com

Web page address

Tabriz University of Medical Sciences, Tabriz
University, Golgasht street, Azadi street, Tabriz

City

Tabriz

Postal code**Phone**

+98 41 3337 9529

Fax

+98 41 3337 9527

Email

Nasimir@tbzmed.ac.ir; Modir7060@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Traditional Medicine, Tabriz University of
Medical Sciences

Full name of responsible person

Ramin Nasimi Doost Azgomi

Position

Ph.D candidate of Traditional Medicine

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

School of Traditional Medicine, Central Library of

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