Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 41 3337 9529

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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 begining of the trial,90 days after the intervention
Method of measurement
Sperm analysis

2

Description
Sperm motility
Timepoint
At the begining of the trial,90 days after the intervention
Method of measurement
Semen analysis

3

Description
sperm morphology
Timepoint
At the begining of the trial,90 days after the intervention
Method of measurement
Semen analysis

4

Description
Semen volume
Timepoint
At the begining 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
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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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Imam Reza hospital, Tabriz University of Medical Sciences
Full name of responsible person
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Position
Urologist, kidney transplant fellowship, professor
Other areas of specialty/work

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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