Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of multiple oral supplements on sperm parameters in men with reproductive disorders compared with control

Protocol summary

Study aim
Investigating the effect of supplements on sperm parameters (motility, number, density, vitality, morphology and chromatin) in infertile male before and after treatment

Design
A clinical trial with a group of patients receiving herbal supplements before and after for 90 days, with only groups, not blind, randomized, phase 2 on 50 patients.

Settings and conduct
Infertile male refer to Yazd Research Institute of Reproductive Sciences, with a mean age of 28.5 years (range 20–45 years) presenting with male factor infertility (primary or secondary) for at least 1 year. All patients give informed consent and are free to withdraw from the trial at any point. They are questioned about medical and surgical history and about alimentary diet. Patients are given an oral daily (2 capsules, twice daily) for 3 months. we do a semen analysis before treatment and another semen analysis at the end of 90 days of treatment.

Participants/Inclusion and exclusion criteria
oligoasthenoteratospermia men with no history of smoking, alcohol and addiction, no history of systemic disease such as diabetes and thyroid disease, cerebrovascular disease and no history of chemotherapy and genital tract infection, taking antioxidant supplements in the last three months and during the study, taking chemical drugs during the study

Intervention groups
Patient group including infertile oligoasthenoteratospermia men

Main outcome variables
Improving sperm parameters, improving male infertility, losing body weight

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221120056545N1**
Registration date: **2023-01-11, 1401/10/21**
Registration timing: **prospective**

Last update: **2023-01-11, 1401/10/21**
Update count: **0**

Registration date
2023-01-11, 1401/10/21

Registrant information

Name
mahdie Hemati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3730 4850

Email address
m.hemati1420@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of multiple oral supplements on sperm parameters in men with reproductive disorders compared with control

Public title
supplement in infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile men who do not have children after one year of intercourse.
Exclusion criteria:
Age
From **20 years** old to **45 years** old
Gender
Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
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
Ethics Committee of Yazd Reproductive Sciences Institute
Street address
BouAli Ave, Safaeie, Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2022-09-04, 1401/06/13
Ethics committee reference number
IR.SSU.RSI.REC.1401.012

Health conditions studied

1

Description of health condition studied
Infertile male
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
sperm parameters
Timepoint
Measurement of sperm parameters before and after 90 days of taking supplement
Method of measurement
Measurement of sperm parameters with microscope and kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infertile male who take the supplement (two pills in the morning and at night for 90 days).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Sciences Institute
Full name of responsible person
Dr Mahdie Hemati, Mr Majid Naghib zade, Dr Alimohammad Abdoli
Street address
Bou Ali Ave., Safaeie., Yazd Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Yazd Reproductive Sciences Institute

Full name of responsible person
Vice President of Research and Technology

Street address
Yazd Reproductive Sciences Institute, Bu Ali St, Safaiyeh

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Yazd Reproductive Sciences Institute

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr. Ali Mohammad Abdoli, Dr. Mahdie Hemati, Mr. Majid Naghibzadeh

Position
Doctor, researcher, researcher

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

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Full name of responsible person
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Position
Doctor, researcher, researcher

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Person responsible for updating data

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researcher

Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available