

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Phone**

+98 35 3824 7087

**Email**

m.hemati1420@gmail.com

## 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

**City**

yazd

**Province**

Yazd

**Postal code**

8916877391

**Phone**

+98 35 3824 7085

**Email**

m.hemati1420@gmail.com

**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

**Street address**

Yazd Reproductive Sciences Institute, Bu Ali St,  
Safaiyeh

**City**

yazd

**Province**

Yazd

**Postal code**

8916877391

**Phone**

+98 35 3824 7085

**Email**

m.hemati1420@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd Reproductive Sciences Institute

**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

**Street address**

Yazd Reproductive Sciences Institute, Bu Ali St,  
Safaiyeh

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Phone**

+98 35 3824 7085

**Email**

m.hemati1420@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Mahdie Hemati

**Position**

researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

**Street address**

Yazd Reproductive Sciences Institute, Bu Ali St,  
Safaiyeh

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Phone**

+98 35 3824 7085

**Email**

m.hemati1420@gmail.com

**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