

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Evaluation of the effect of *Boswellia serrata* Roxb. ex Colebr. oleogum resin on sperm motility in men with sperm motility defects (asthenospermia)

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of frankincense oleogum resin on improving sperm motility in men with asthenospermia

##### Design

This study is a double-blind clinical trial with control group and intervention group in which 50 patients are randomly assigned to one of these two groups.

##### Settings and conduct

The study site is Yazd Infertility Research and Treatment Center

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include willingness to cooperate, at least one year has passed since the decision to have a child and not to use contraceptives, men 20 to 45 years old, asthenospermia of unknown cause (idiopathic) according to the criteria of the World Health Organization and exclusion criteria including men with infertility with a specific cause (such as hormonal disorders), infertility of the wife, drug and alcohol use, underlying diseases like diabetes, kidney disease, chronic liver disease

##### Intervention groups

The control group receives a placebo and the intervention group receives a capsule containing frankincense

##### Main outcome variables

Sperm motility

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140817018828N7**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-08-24, 1399/06/03**

Update count: **0**

##### Registration date

2020-08-24, 1399/06/03

##### Registrant information

###### Name

Alimohammad Ranjbar

###### Name of organization / entity

Yazd University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3820 3419

###### Email address

amranjbar@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-24, 1399/06/03

##### Expected recruitment end date

2020-12-23, 1399/10/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of *Boswellia serrata* Roxb. ex Colebr. oleogum resin on sperm motility in men with sperm motility defects (asthenospermia)

##### Public title

Evaluation of the effect of *Boswellia serrata* Roxb. ex Colebr. oleogum resin on sperm motility in men with

sperm motility defects (asthenospermia)

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willingness to cooperate At least one year has passed since the decision to have a child and not to use contraceptives Idiopathic asthenospermia according to WHO criteria

### Exclusion criteria:

Men with infertility with a specific cause (such as hormonal disorders) Infertility of the wife Drug and alcohol use Having underlying diseases such as diabetes, kidney disease (creatinine more than 2 times), chronic liver disease Taking antioxidant supplements in the last three months

## Age

From **20 years** old to **45 years** old

## Gender

Male

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Limited randomization according to the law of random allocation in such a way that out of 50 cases, 25 people were selected by lot for the group receiving frankincense and the rest were placed in the group receiving placebo. Allocation concealment was performed by opaque seals in random sequence.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants, outcome assessor, clinical caregiver

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee in Research of Shahid Sadoughi Medical School of Yazd

##### Street address

Profesor hesabi Blvd.

#### City

Yazd

#### Province

Yazd

#### Postal code

8915173149

#### Approval date

2019-11-03, 1398/08/12

#### Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.216

## Health conditions studied

### 1

#### Description of health condition studied

Asthenospermia

#### ICD-10 code

R86.9

#### ICD-10 code description

asthenospermia

## Primary outcomes

### 1

#### Description

Sperm motility

#### Timepoint

Before the intervention and 84 days after taking the drug or placebo

#### Method of measurement

Sperm test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: This group receives 2 placebo capsules containing cellulose per day for 84 days. In addition to this treatment, patients take 1 tablet of folic acid 5 mg daily

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: This group takes 2 capsules a day containing 500 mg of frankincense for 84 days. In addition to this treatment, patients take 1 tablet of folic acid 5 mg daily

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**  
Yazd Infertility Center

**Full name of responsible person**  
Seyed Alimohammad Mirjalili

**Street address**  
Bou ali Ave., Timsar fallahi Ave.

**City**  
Yazd

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000

**Phone**  
+98 35 3824 7085

**Email**  
ivf@ssu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Yazd University of Medical Sciences

**Full name of responsible person**  
Hooshang Mehrparvar

**Street address**  
Bahonar Square, Yazd, Iran

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Yazd

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8917693571

**Phone**  
+98 35 3724 0171

**Email**  
ah.mehrparvar@gmail.com

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**  
Yazd University of Medical Sciences

**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**  
Alimohamad Ranjbar Jamal abadi

**Position**  
Assistant Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Medical Pharmacy

**Street address**  
Professor Hesabi Boolvar, Yazd, Iran

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**Web page address**

## Person responsible for scientific inquiries

#### Contact

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**Position**  
Assistant Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Yazd University of Medical Sciences

**Full name of responsible person**

Fateme Paydar

**Position**

Pharmacy student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

The end of Professor Hesabi Boulevard

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yazd

**Province**

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**Postal code**

8915173149

**Phone**

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**Email**

fatemeh75paydar@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available