

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Analysis of sesame effect on parameters of sperm in infertility of men due to oxidative stress agents in Hamadan.

Protocol summary

Study aim

Study of the effects of sesame seeds on oxidative stress and sperm parameters in semen samples of males with infertility related to oxidative stress in Hamedan.

Design

In this study, 50 patients with idiopathic infertility who have been admitted to Fatemeh Hospital of Hamadan are selected randomly and treated with sesame for a period of 3 months. It should be noted that sperm samples are collected before and after of treatment.

Settings and conduct

The sperm Samples of the patient after collecting in Fatemeh Hospital will be transferred to the Biochemistry Lab of Hamedan University of Medical Sciences to evaluate the oxidative and antioxidant tests.

Participants/Inclusion and exclusion criteria

Entry requirements include participants aged 29 to 40 with idiopathic infertility. Exclusion criteria for the study include those who are allergic to sesame seeds and azoospermic patients.

Intervention groups

The control group in this study was the patients before the intervention and the patient group included those who were under the intervention for 3 months.

Main outcome variables

Improvement of sperm parameters; Reduction of oxidative stress in sperm samples; Increasing antioxidant agent in sperm samples; Reducing sperm DNA damage

General information

Reason for update

Acronym

HIS

IRCT registration information

IRCT registration number: **IRCT20171002036508N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

hadi ghasemi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 918 906 7823

Email address

h.ghasemi@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

supported by Hamadan University of Medical Sciences.

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analysis of sesame effect on parameters of sperm in infertility of men due to oxidative stress agents in Hamadan.

Public title

the effect of sesame on men infertility treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Idiopathic infertility being 29-40 years old Lack of underlying diseases

Exclusion criteria:

Azoospermia Allergic reactions to sesame seeds Patient with dissatisfaction to participation in the study or to continue Individuals who have been used sesame seeds or its oil at the last three months

Age

From **29 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

The first sample is taken before the intervention and the next sample is taken after intervention

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

Hamadan University of Medical Sciences

Street address

Fahmideh Blvd. Mahdieh Ave., Hamadan-Iran

City

Hamadan

Province

Hamadan

Postal code

۶۵۶۷۱۷۱۶۳۵

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.UMSHA.REC.13960.252

Health conditions studied

1

Description of health condition studied

Male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

DNA Fragmentation

Timepoint

Before the study and three months after the intervention began

Method of measurement

observation of DNA fragmentation with microscope

2

Description

sperm parameters

Timepoint

Before the study and three months after the intervention began

Method of measurement

evaluation of sperm motility and sperm morphology with CASA software

Secondary outcomes

1

Description

Total antioxidant capacity

Timepoint

Before the study and three months after the intervention began

Method of measurement

mmol/L measurement with commercial kit

2

Description

Total protein

Timepoint

Before the study and three months after the intervention began

Method of measurement

mg/dl measurement with bradford method

3

Description

Malondialdehyde

Timepoint

Before the study and three months after the intervention began

Method of measurement

nmol/ml measurement with commercial kit

4

Description

Total oxidant status

Timepoint

Before the study and three months after the intervention began

Method of measurement

mmol/L measurement with commercial kit

Intervention groups

1

Description

intervention group consumed 30 grams of sesame prescribed for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Fatemieh Hospital-Hamedan-IRAN

Full name of responsible person

Dr. Iraj Amiri

Street address

District 1, Hamedan, Hamadan Province

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6567171635

Phone

+98 81 5822 4372

Fax

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Email

amiri@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Dr.Saeed Bashirian

Street address

Fahmideh Blvd. Mahdieh Ave., Hamadan-Iran

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Email

s-bashirian@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamadan 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**

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Iraj Amiri

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Fax**Email**

amiri@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Dr Mohammad ali AmirZargar

Position

Urologist

Latest degree

Specialist

Other areas of specialty/work

Urology

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Web page address**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the main outcome and the subordinate outcome, as well as data like the age that can not be identified, will be shared.

When the data will become available and for how long

The acceptability course will begin 5 months after the results printed.

To whom data/document is available

Access to published data will be possible for academic workers.

Under which criteria data/document could be used

Individuals working with healthcare organizations will be able to use the data to treat or assist the patient's treatment process.

From where data/document is obtainable

If necessary, access to the data can be obtained by contacting Dr. Iraj Amiri by e-mail; amiri@umsha.ac.ir

What processes are involved for a request to access data/document

Dear Applicants for access the related data can contact our colleagues by e-mail, they must submit confirmation and receive the data by submitting an academic email and an undertaking to prove that they do not misuse the data. It takes a maximum of 10 days.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Hadi ghasemi

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Biochemistry

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