Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 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 Fatemieh 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 Fatemieh 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 measurment with commercial kit

2

Description

Total protein

Timepoint

Before the study and three months after the intervention began

Method of measurement

mg/dl measurment with bradford method

3

Description

Malondialdehyde

Timepoint

Before the study and three months after the intervention began

Method of measurement

nmol/ml measurment with commercial kit

4

Description
Total oxidant status
Timepoint
Before the study and three months after the intervention began
Method of measurement
mmol/L measurment 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
City
Hamadan
Province
Hamadan
Postal code
6567171635
Phone
+98 81 5822 4372
Fax
+98 81 5822 4372
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
City
Hamadan
Province
Hamadan
Postal code
6567171635
Phone
+98 81 5822 4372
Fax
+98 81 5822 4372
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
Street address
Fahmideh Blvd. Mahdieh Ave., Hamadan-Iran
City
Hamadan
Province
Hamadan
Postal code
6567171635
Phone
+98 81 3827 7013
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
Street address
Fahmideh Blvd. Mahdieh Ave., Hamadan-Iran
City
Hamadan
Province
Hamadan
Postal code
6567171635
Phone
+98 81 3827 7013
Fax
Email
amirzargar@umsha.ac.ir
Web page address

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
Street address
Fahmideh Blvd. Mahdieh Ave., Hamadan-Iran
City
Hamadan
Province
Hamadan
Postal code
6567171635
Phone
+98 81 3827 7013
Fax
Email
hadigh110@gmail.com
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