

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the Effectiveness of Astaxanthin on Induced Amount of ROS in Semen and Sperm Quality Among Patients with Varicocele through Nrf2/Keap1 Pathway

Protocol summary

Study aim

Determination the Effectiveness of Astaxanthin on Induced Amount of ROS in Semen and Sperm Quality Among Patients with Varicocele through Nrf2/Keap1 Pathway

Design

This Triple-blind randomized clinical trial, controlled by placebo, based on the guidelines contained in the Helsinki Declaration, after obtaining permission from the ethics committee of Tehran University of Medical Sciences, 50 patients will be recruited. Prior to the intervention, written informed consent will be obtained from all participants

Settings and conduct

The location of the experiment: Tehran University of Medical Sciences. Sampling location: Royan Institute. Varicocelectomy; Collection of semen; Assessment of the expression of NRF2-Keap1 pathway genes in sperm cells; Biochemical evaluation in seminal plasma.

Participants/Inclusion and exclusion criteria

Inclusion Criteria • Varicocele II & III • One or more Seminal characteristics lower value • Age: older than 20
Exclusion Criteria • Varicocele I • Previous varicocele surgery • Receiving a medical treatment affecting fertility for previous 3 months • Testicular cancer and trauma • Alcoholic, Drugs • HIV

Intervention groups

Astaxanthin consumer. Placebo consumer.

Main outcome variables

NRF2-Keap1 pathway genes, Semen quality, Biochemical parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230924059501N1**

Registration date: **2023-11-06, 1402/08/15**

Registration timing: **retrospective**

Last update: **2023-11-06, 1402/08/15**

Update count: **0**

Registration date

2023-11-06, 1402/08/15

Registrant information

Name

Shimal Mohammed Salih

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 901 050 7977

Email address

shimalayub@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-25, 1401/03/04

Expected recruitment end date

2023-11-01, 1402/08/10

Actual recruitment start date

2022-06-01, 1401/03/11

Actual recruitment end date

2023-11-01, 1402/08/10

Trial completion date

2023-11-01, 1402/08/10

Scientific title

Investigating the Effectiveness of Astaxanthin on Induced Amount of ROS in Semen and Sperm Quality Among Patients with Varicocele through Nrf2/Keap1 Pathway

Public title

Astaxanthin in Varicocele

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Varicocele II & III One or more Seminal characteristics
lower value Age: older than 18

Exclusion criteria:

Varicocele I Previous varicocele surgery Receiving a
antioxidants affecting fertility for previous 3 months
Testicular cancer and trauma Alcoholic, Drugs HIV

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

More than 1 sample in each individual

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

Semen collection before and 3 months after
varicocelectomy

Actual sample size reached: **43**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Semen collection before and 3 months after
varicocelectomy

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly assigned to the study after visiting the gynecology clinic. Randomization will be in the form of blocking in such a way that the method of replacement blocks is used within each floor. The blocks will be binary, consisting of AB and BA. The randomization tool will be a table of random numbers, that using the sequence AB for numbers zero through 4 in the random number table and the sequence BA for 5 to 9. It should be noted that the letter A means the intervention group and the letter B means the control group. For hiding we use concealment allocation in a way that before the individual is assigned, the assigned group is not specified. In this method, each of the random sequences created on a cards are placed in the closed envelopes. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the time of registration of participants, based on the order of entry of the eligible participants in the study, one of the closed envelopes will be opened and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be a three-way blind and the patient, researcher and statistical analyst of the patients' group therapy have no information and the decoder is outside the research team. The drug under study (Astaxanthin) and placebo in a completely similar shape and appearance, each of which is 60 in the same bottle instead of the drug will be provided to the subjects based on random allocation. It should be noted that the drug content of each The bottles are code-tagged on the bottles by the by someone outside the research team consultant and the research team is not aware of their interpretation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical
Sciences

Street address

Building no.1, Northern gate of the university,
Poursina St. Qods St. Enqelab St

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-08-13, 1401/05/22

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.354

Health conditions studied**1****Description of health condition studied**

varicocele

ICD-10 code

I86.1

ICD-10 code description

Scrotal varices

Primary outcomes**1****Description**

semen parameters
Timepoint
Before and 90 days after intervention
Method of measurement
Semen analysis according to the World Health Organization (WHO) criteria

2

Description
Biochemical and inflammation factors
Timepoint
90 days after the beginning of the intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
NRF2-KEAP1 pathway genes
Timepoint
90 days after the beginning of the intervention
Method of measurement
RealTime PCR

Intervention groups

1

Description
Intervention group: Astaxanthin consumption. In this group, patients take 6 mg of astaxanthin (1 capsule/day) for 90 days. Their routine treatment does not stop.
Category
Treatment - Drugs

2

Description
Control group: Placebo consumption. In this group, patients take 6 mg of placebo (1 capsule/day) for 90 days. Their routine treatment does not stop.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Dr. Mohammad Ali Sedighi Gilani
Street address
No. 12, Royan Alley., Hafez St., Banihashem St.,
Qasem Soleimani Expressway (Resalat Ave)., Tehran,
Iran
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Postal code
1314744513
Phone
+98 21 2356 2000
Email
info@royaninstitute.org

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr.Mohammad Ali Sahraian
Street address
Tehran University of Medical Sciences, Keshavarz
blvd. Ghods st.
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Email
tums_edu@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Fardin Amidi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work

Anatomy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Shimal Mohammed Salih

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Reproductive Biology

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Person responsible for updating data

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Full name of responsible person

Shimal Mohammed Salih

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Latest degree

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Other areas of specialty/work

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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

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

Yes - There is 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

Title and more details about the data/document

All data obtained in the research will be published in one
of the valid and related scientific journals.

**When the data will become available and for how
long**

Spring 2024

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data of this study can be used as an adjuvant
therapy in patients with Varicocele.

From where data/document is obtainable

Shimal Mohammed Salih

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

By sending an email to the corresponding author.

Comments