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 QualityAmong 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 QualityAmong 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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Tehran

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1314744513

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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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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

Name of organization / entity
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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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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