Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of Lycopene and FruHis supplementation on serum levels of prostate specific antigen (PSA) and clinical outcomes in Benign Prostate Hyperplasia (BPH) patients

Protocol summary

Study aim

Main Objective: To determine the effect of Lycopene and Fruhis supplementation on plasma PSA levels and clinical parameters in patients with BPH. Sub-objectives of the project: Determining the effect of lycopene and FruHis supplementation on prostate size in patients with BPH Determining the effect of lycopene and Fruhis supplementation on serum PSA and Free PSA levels in patients with BPH Determining the effect of lycopene and FruHis supplementation on the factors affecting prostate cell proliferation (IGF-1) in patients with BPH Practical goals of the project: If the hypotheses of this study are met, we can help increase the effectiveness of common supplements for patients with BPH by conducting additional studies and further studies, by adding FruHis to lycopene supplements.

Design

double blind randomized clinical trial with a parallel group design

Settings and conduct

Sampling will be done at Imam Khomeini Hospital in Tehran. Sampling will be done using available method and based on inclusion criteria. People who will be involved in sampling and statistical analysis will not be aware of the code of individuals and their placement in the study groups, and randomization will be done by someone else (in charge of the College Lab) who is not participating in the study.

Participants/Inclusion and exclusion criteria

Patients with BPH, aged between 50-75, were diagnosed by Urologist that have negative DRE test. People with prostate cancer or other malignancies who have been taking finasteride or other anti-androgen drugs for the past 6 months and also allergic to tomatoes will not be included in the study.

Intervention groups

1) Lycopene and FruHis supplementation group 2) Lycopene supplementation group 3) FruHis supplementation group and 4) Control group

Main outcome variables

PSA, IGF-1,Severity of disease and quality of life of patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190522043669N1**
Registration date: **2021-03-19, 1399/12/29**
Registration timing: **retrospective**

Last update: **2021-03-19, 1399/12/29**
Update count: **0**

Registration date

2021-03-19, 1399/12/29

Registrant information

Name

Alireza Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Lycopene and FruHis supplementation on serum levels of prostate specific antigen (PSA) and clinical outcomes in Benign Prostate Hyperplasia (BPH) patients

Public title
The Effect of Lycopene and FruHis supplementation on serum levels of PSA in BPH patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with BPH, whose disease is diagnosed by an urologist, range in age from 50 to 75 years. a serum PSA level between 4-10 ng / ml and have a negative DRE test. Negative DRE test.
Exclusion criteria:
Use of Finasteride or other anti-androgen drugs for the last 6 months. Prostate cancer and other malignancies such as skin, myeloma and bladder cancers. Chronic diseases such as severe liver disease and renal failure. Bladder and kidney stones. Lycopene supplementation in the last 6 months Any allergies and sensitivities to tomatoes or tomato products
Age
From **50 years** old to **75 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Before intervention, subjects were first stratified by age (55-60 years and 60-75 years), BMI (25≥ BMI and 25≤ BMI) and opium consumption (with or without) by stratified randomization method and There will be in the binary blocks. Subjects were randomly assigned to four groups: 1- Lycopene and FruHis supplementation group (1 capsule daily containing 25 mg lycopene and one capsule containing 10 mg FruHis) 2- Lycopene supplementation group (2 capsules daily containing 25 mg lycopene) 3- FruHis Supplementation group (2 capsules daily containing 10 mg FruHis) 4- Control group (2 capsules similar other groups). For the purpose of random allocation, the code of individuals who are matched for the three variables mentioned is first poured into pots and the matched individuals are randomly divided into intervention groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Researchers involved in sampling and statistical analysis will not be aware of the code of individuals and their placement in the study groups, and randomization will be done by someone else (university lab officer) not involved in the study. The medical team, the data monitoring safety committee, will also be aware of the blinding process. Blinding: The patient takes the supplements (intervention groups or placebo groups) in enclosed packages. Coded by one of the partners' designs It takes place and blinds the doctor, the administrator and the patient.
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
Flat. 6, Office Building of Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1417933331
Approval date
2019-02-12, 1397/11/23
Ethics committee reference number
IR.TUMS.VCR.REC.1397.951

Health conditions studied

1

Description of health condition studied
Benign Prostate Hyperplasia
ICD-10 code
D29.1
ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
serum PSA Levels
Timepoint
at the baseline and end of intervention
Method of measurement
Immuno Chemi Luminance

2

Description
serum free-PSA Levels
Timepoint
at the baseline and end of intervention
Method of measurement
Immuno Chemi Luminance

3

Description
serum IGF-1 Levels
Timepoint
at the baseline and end of intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
Severity of illness
Timepoint
at the baseline and end of intervention
Method of measurement
International Prostate Symptom Score(IPSS) questionnaire

2

Description
Quality of life
Timepoint
at the baseline and end of intervention
Method of measurement
International Prostate Symptom Score(IPSS) questionnaire

Intervention groups

1

Description
Intervention group: Lycopene and FruHis supplement group (1 capsule daily containing 25 mg lycopene and 10 mg FruHis)
Category
Treatment - Drugs

2

Description
Intervention group: Supplementation group of FruHis (2 capsuleس daily containing 10 mg FruHis)
Category
Treatment - Drugs

3

Description
Intervention group: Lycopene supplementation group (2 capsules daily containing 25 mg lycopene)
Category
Treatment - Drugs

4

Description
Control group: placebo group
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Reza Nowroozi
Street address
Imam Khomeini Hospital, Dr.Gharib Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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No. 44, Hojatdost Ave, Naderi Ave, Keshavarz Blvd, Tehran city
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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
Alireza Sadeghi
Position
Ph.D student of nutrition
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document

The study protocol will be written and published in the form of an article. Clinical report of our study will be published after finishing data gathering

When the data will become available and for how long

3 months after end of study

To whom data/document is available

The study findings will be made available to the general public

Under which criteria data/document could be used

For use in clinic or written a review article. For original studies, it will be permitted if they acknowledge our study personnel

From where data/document is obtainable

Using Email, by author who are responsible for updating data

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

After receiving application by the author who are responsible for updating data and following consultation with scientific consultant, data will be provided

Comments