Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Nov 2026

Extraction of lycopene from tomatoes and formulation of lycopene tablets and stability studies and investigation of its antioxidant effects clinically.

Protocol summary

Study aim
Investigating the clinical effects of lycopene in patients with metabolic syndrome.

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3 on 90 patients. rand function in SPSS software was used for randomization.

Settings and conduct
the sampling location will be Qaim Hospital-Nutrition Clinic.clinical trial on metabolic syndrome patients that divided into receiving lycopene tablets and control group.after collecting the samples, tests such as the level of antioxidants in serum by PAB test, level of cytokines, lipid profile will be checked and their results will analyzed statistically. The study is three-way blind. The participants, doctor, data analyzer are also unaware of the tatmnt group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Men and women between the ages of 18 and 60 years. - Living in Mashhad. - Satisfaction and expression of the desire to participate in the plan. Having metabolic syndrome according to the IDF index, plus two of the following: 1. Fasting blood sugar higher than 100 mg/dL or having diabetes. 2. Triglyceride is higher than 150 mg/dL. 3. Systolic blood pressure of 130 mm Hg or diastolic blood pressure higher than 85 mm Hg or the use of antihypertensive drugs. 4. HDL-C less than 40 mg/dL in men and less than 50 mg/dL in women. Exclusion criteria: - Pregnancy or breastfeeding. - Chronic heart patients. - Patients whose medications may interact with lycopene. - History of taking complementary medicines in the last 6 months.

Intervention groups
Drug intervention group: Receiving 20 mg lycopene tablets for 60 days along with a diet Control group: Receiving a placebo for 60 days along with a diet

Main outcome variables
Prooxidant-antioxidant balance in blood serum, Measuring lipid profile in blood serum, Examining the level of inflammatory and pro-inflammatory cytokines, Anthropometric studies

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130507013263N3**
Registration date: **2022-10-14, 1401/07/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-14, 1401/07/22**
Update count: **0**

Registration date
2022-10-14, 1401/07/22

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 1882 3255

Email address
hadizadehf@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-12-01, 1401/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Extraction of lycopene from tomatoes and formulation of lycopene tablets and stability studies and investigation of its antioxidant effects clinically.

Public title
Investigating the effect of lycopene in metabolic syndrome patients.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Living in Mashhad. Consent and expression of desire to participate in the plan. Having metabolic syndrome based on the IDF index, which is at least two parameters associated with waist circumference (having a waist circumference higher than 94 cm in men and 80 cm in women, having fasting blood sugar higher than 100 mg/dl or having diabetes, Having triglycerides higher than 150 mg/dl, having systolic blood pressure of 130 mm Hg or diastolic blood pressure higher than 85 mm Hg or using antihypertensive drugs, having HDL less than 40 mg/dl in men and less than 50 mg/dl in women). Men and women between the ages of 18-60 years.

Exclusion criteria:
Pregnancy or breastfeeding. volunteers who have a history of taking complementary medicines in the last 6 months. volunteers with chronic heart diseases. Patients taking medications that may interact with lycopene.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be determined by random block method with blocks of 4 and using random numbers table of Random Allocation Software. Blocking and allocation sequence for concealment will be done by a person not involved in the research. The allocation ratio of the samples will be (Allocation 1:1) and will be placed in two groups (Assignment). Then, based on the obtained blocks and according to the allocation sequence, the drugs will be given to the patients.The working method is that we determine the number of blocks according to the sample size. Each block is numbered and is used for 4 patients. For example, if block number 2 is selected in the lottery and its treatment group is ABAB, the first patient will receive treatment A, the second patient will receive treatment B, the third patient will receive treatment A, and the fourth patient will receive treatment B.

Blinding (investigator's opinion)
Double blinded

Blinding description
To blind the participants, a placebo will be used with packaging, color, size and other appearance characteristics completely similar to lycopene tablets. In order to blind the evaluators of the research team, as soon as the treatment or control group is determined in the randomization stage, a random code will be assigned to the participant (without including group A or B on the file) and they will be followed by this code in any stage of research. Finally, after evaluating and documenting the results ,the codes will be decoded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
No. 59, Qods 9th St., Malekabad Blv., Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9185775491

Approval date
2017-05-04, 1396/02/14

Ethics committee reference number
IR.MUMS.SP.1396.214

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
Metabolic syndrome

Primary outcomes

1

Description
Prooxidant-antioxidant balance in blood serum of volunteers

Timepoint
The beginning of the study (before the start of the intervention) and the end of the study (60 days later)
Method of measurement
Using PAB kit and measurement in blood serum

2

Description
Measuring lipid profile in blood serum
Timepoint
The beginning of the study (before the start of the intervention) and the end of the study (60 days later)
Method of measurement
Using a lipid profile assay kit and measuring the concentration of LDL, HDL, TG and total cholesterol in blood serum

3

Description
Examining the level of inflammatory and pro-inflammatory cytokines
Timepoint
The beginning of the study (before the start of the intervention) and the end of the study (60 days later)
Method of measurement
Using ELISA kits to measure the level of cytokines IL-4, IL-6, IL-10, IFNγ, MCP-1, TNFα in blood serum.

4

Description
Anthropometric studies
Timepoint
at the beginning of the study (before the start of the intervention), in the middle of the study (30 days later) and at the end of the study (60 days later)
Method of measurement
By using the InBody device and measuring parameters such as the percentage of body fat and muscle of the volunteers

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily intake of one pill containing 20 mg of antioxidant lycopene extracted from tomato paste and formulated in the first phase of this study for 60 days. each volunteer in this group receives a specific food plan designed by a nutritionist for 60 days.
Category
Treatment - Drugs

2

Description
Control group: Receiving daily placebo tablets for 60 days.In addition to the placebo, each volunteer in this group receives a specific diet plan designed by a nutritionist for 60 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qaem hospital
Full name of responsible person
Mahdi Mirahmadi
Street address
No 59, Qods 9th St., Malekabad Blv., Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9185775491
Phone
+98 915 301 5103
Fax
+98 51 3766 6279
Email
miram951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farzin Hadizadeh
Street address
Department of Chemical Pharmacology, School of Pharmacy, Mashhad University of Medical Sciences, Corpus of University, Azadi Sq., Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 915 311 4406
Email
hadizadehf@mums.ac.ir
Grant name
Dr. Farzin Hadizadeh
Grant code / Reference number
960774
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mahdi Mirahmadi

Position
Resident

Latest degree
Master

Other areas of specialty/work
Medical Pharmacy

Street address
No. 59, Qods 9th St., Malekabad Blv., Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9185775491

Phone
+98 51 3766 6279

Email
miram951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Farzin Hdizadeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Department of Chemical Pharmacology, School of Pharmacy, Mashhad University of Medical Sciences (MUMS), Vakilabad Blv., Azadi Sq., Mashhad.Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948954

Phone
+98 51 3255 1882

Fax
+98 51 3251 1882

Email
hadizadehf@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahdi Mirahmadi

Position
Resident

Latest degree
Master

Other areas of specialty/work
Medical Pharmacy

Street address
No. 59, Qods 9th St., Malekabad Blv., Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9185775491

Phone
+98 51 3766 6279

Email
miram951@mums.ac.ir

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
Undecided - It is not yet known if there will be 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
- Data related to anthropometric information of volunteers. - Data on the lipid profile of the volunteers before and after entering the study. - Data on pro-antioxidant and antioxidant balance of volunteers, before and after entering the study. - Data on the level of inflammatory and pro-inflammatory cytokines in patients.

When the data will become available and for how long

From the beginning of 2024

To whom data/document is available

The Research Council of Mashhad University of Medical Sciences will determine it.

Under which criteria data/document could be used

To use the information of this study in other research projects

From where data/document is obtainable

Vice Chancellor of University Research and Technology Address: Vice Chancellor of University Research and Technology, Qureishi Building, next to Howeizeh Cinema, Mashhad, Iran. Phone: +985138411538 Fax: +985138430249 Postal code: 9138813944 Email: vcresearch@mums.ac.ir

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

Sending a written request to the plan's executors or obtaining permission from the Research and Technology Vice-Chancellor of Mashhad University of Medical Sciences.

Comments