Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of astaxanthin supplementation on the plasma and cellular levels of magnesium, zinc, copper and selenium in patients with type 2 diabetes treated by metformin

Protocol summary

Study aim

Evaluation the effect of astaxanthin supplementation on the plasma and cellular levels of magnesium, zinc, copper and selenium in patients with type 2 diabetes treated by metformin

Design

Clinical trial with control group and placebo group, parallel, double blind, randomized, phase 3 and study on 50 patients. SPSS software will be used to generate random numbers.

Settings and conduct

The study population was from patients referring to Endocrine and Metabolism Research Center of Isfahan and conducted tests at the Faculty of Pharmacy of Isfahan University of Medical Sciences. The cellular and plasma levels of magnesium, zinc, copper and selenium are measured in two groups of treatment and control before and 8 weeks after treatment

Participants/Inclusion and exclusion criteria

Inclusion criteria: type 2 diabetic patients treated by metformin Exclusion criteria: patients with type 1 diabetes, Pregnant women. Women in lactation, Taking any antidiabetic drug other than metformin, Patients with other endocrine disorders, Take any other antioxidant supplement

Intervention groups

One group will be taken metformin (1000-1500 mg/day) plus astaxanthin supplementation 10 mg/day and other groups will be taken metformin 1500-1000 mg/day plus placebo For 12 weeks All steps for the treatment process are under the supervision of a doctor.

Main outcome variables

Trace elements of magnesium, zinc, copper and selenium at the cellular and plasma levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190305042939N3**
Registration date: **2022-11-10, 1401/08/19**
Registration timing: **prospective**

Last update: **2022-11-10, 1401/08/19**
Update count: **0**

Registration date

2022-11-10, 1401/08/19

Registrant information

Name

Mohamad hosein aarabi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation the effect of astaxanthin supplementation on the plasma and cellular levels of magnesium, zinc, copper and selenium in patients with type 2 diabetes treated by metformin

Public title
Evaluating the effect of astaxanthin supplement on the levels of trace elements in patients with type 2 diabetes treated with metformin

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with type 2 diabetesTreated by metformin Age: 20-60 years

Exclusion criteria:
Patients with type 1 diabetes Pregnant women Women in lactation Taking any anti diabetic drug other than metformin Patients with other endocrine disorders Take any other antioxidant supplement

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
From among patients in the Isfahan Endocrine and Metabolism Center, 50 patients with type 2 diabetes who are merely treated with metformin are selected available and easy to use.Then, the names of the patients were entered into the SPSS software and using the software, they are randomly divided into two groups of 25 intervention and placebo groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
For this purpose, based on the supplement we used in this intervention, which is the softgel, the placebo is designed and the investigator is aware of the difference between the two, but the patients and the statistical counselor do not know this difference.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Deputy of Research & Technology, Headquarters Building No. 4, Isfahan University of Medical Sciences & Health Services, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2022-08-10, 1401/05/19

Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.181

Health conditions studied

1

Description of health condition studied
Type 2 Diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Cellular levels of magnesium

Timepoint
Before and at the end of intervention

Method of measurement
Atomic absorption analysis

2

Description
Cellular levels of zinc

Timepoint
Before and at the end of intervention

Method of measurement
Atomic absorption analysis

3

Description
Cellular levels of copper

Timepoint
Before and at the end of intervention

Method of measurement
Atomic absorption analysis

4

Description
Cellular levels of selenium
Timepoint
Before and at the end of intervention
Method of measurement
Atomic absorption analysis

Secondary outcomes

1

Description
Plasma levels of magnesium
Timepoint
Before and at the end of intervention
Method of measurement
Atomic absorption analysis

2

Description
Plasma levels of Zinc
Timepoint
Before and at the end of intervention
Method of measurement
Atomic absorption analysis

3

Description
Plasma levels of copper
Timepoint
Before and at the end of intervention
Method of measurement
Atomic absorption analysis

4

Description
Plasma levels of selenium
Timepoint
Before and at the end of intervention
Method of measurement
Atomic absorption analysis

Intervention groups

1

Description
Intervention group: Astaxanthin supplement; For 8 weeks, they will receive one 10 mg astaxanthin soft gel tablet daily.
Category
Treatment - Other

2

Description
Control group: They will receive 1 placebo tablet containing starch daily for 8 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and Metabolism Research Center of Isfahan University of Medical Sciences
Full name of responsible person
Mohammadhosein Aarabi
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Sponsors / Funding sources

1

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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
Esfahan 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

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable