

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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

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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 diabetes Treated 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

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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

Sponsor

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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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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 FormUndecided - 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