Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation and comparison of the effect of Cinnamon and Chromium Picolinate supplementation on Hemoglobin A1c in Patients with Type 1 Diabetes mellitus.

Protocol summary

Study aim
Finding a treatment to reduce hemoglobin A1C and increase the quality of life of patients with type 1 diabetes mellitus by reducing the insulin consumption.

Design
This study was conducted as a clinical trial with two intervention groups and one control group, parallel, double-blind, randomized on 90 patients.

Settings and conduct
This study was a double-blind, randomized controlled clinical trial which was conducted on patients with type 1 diabetes who were younger than 18 years old referring to Mofid Hospital clinic in 1400. The samples were randomly assigned to three groups receiving cinnamon, chromium picolinate and control group. Researchers and patients were blinded to the contents of the boxes.

Participants/Inclusion and exclusion criteria
Entry conditions: Type 1 diabetes has been diagnosed for 18 months before entering the study. Being less than 18 years old when entering the study. Not being allergic to supplements. Non-entry conditions: No history of medical or psychiatric hospitalization in the last 12 months. Pregnancy or breastfeeding. Hemoglobinopathy. Acute infections (pneumonia, urinary tract infection, otitis).

Intervention groups
The first group: 180 capsules each contains 500 mg cinnamon in Synabetic brand used twice daily. The secondgroup: 90 tablets each contains 200 mcg chromium picolinate of VITABIOTICS brand used once daily. Control group:No intervention and no placebo, just used their routine insulin regime and followed in the same period. These steps were repeated in two 90 days courses and they received supplements for 180 days in total.

Main outcome variables
Body Mass Index; Duration of diagnosis; Fasting Blood Sugar; Hemoglobin A1C; TYG index; Insulin Carbohydrate Ratio; Daily Use of Insulin.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230501058037N1**
Registration date: **2023-06-19, 1402/03/29**
Registration timing: **retrospective**

Last update: **2023-06-19, 1402/03/29**
Update count: **0**

Registration date
2023-06-19, 1402/03/29

Registrant information
Name
Shirin Ghane fard
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2238 9479
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-21, 1401/02/31
Expected recruitment end date
2023-04-20, 1402/01/31
Actual recruitment start date
2022-05-21, 1401/02/31
Actual recruitment end date
2023-04-20, 1402/01/31

Trial completion date
2023-07-22, 1402/04/31

Scientific title
Evaluation and comparison of the effect of Cinnamon and Chromium Picolinate supplementation on Hemoglobin A1c in Patients with Type 1 Diabetes mellitus.

Public title
Effect of Cinnamon and Chromium Picolinate supplementation on Hemoglobin A1c in Patients with Type 1 Diabetes.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Type 1 diabetes has been diagnosed for 18 months before entering the study Patients must be less than 18 years old when entering the study Refer to Mofid hospital clinic for routine care Patients have not taken medicinal plants or other supplements in the last 8 weeks Do not be allergic to supplements
Exclusion criteria:
Patients do not have a history of hospitalization for medical or psychiatric reasons in the last 12 months It is not possible to access by phone Pregnancy or breastfeeding Hemoglobinopathy Acute infection (pneumonia, urinary tract infection, otitis)

Age
To **18 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Due to randomization of participants of this study, we used restricted randomization in type of block randomiztion.Size of blocks were equal and consisted of six participants, two participants in cinnamon, two participants in chromium picolinate and two in control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Cinnamon and Chromium Picolinate were placed in boxes that could not be distinguished by Color, Size and Shape.Researchers and Participants were blinded to the contents of the boxes.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Daneshjoo boulevard, Velenjak street.
City
Tehran
Province
Tehran
Postal code
1983969411

Approval date
2021-11-22, 1400/09/01

Ethics committee reference number
IR.SBMU.MSP.REC.1400.572

Health conditions studied

1

Description of health condition studied
Type 1 diabetes

ICD-10 code
E10.9

ICD-10 code description
Type 1 diabetes mellitus without complications

Primary outcomes

1

Description
Age Of The Patient

Timepoint
At The Beginning Of The Study

Method of measurement
Questionnaire-Clinical File

2

Description
Gender Of The Patient

Timepoint
At The Beginning Of The Study

Method of measurement
Questionnaire-Clinical File

3

Description
Height Of The Patient
Timepoint
At The Beginning Of The Study
Method of measurement
Meter

4

Description
Patient Weight
Timepoint
At The Beginning Of The Study
Method of measurement
Scales

5

Description
Body Mass Index
Timepoint
At The Beginning Of The Study
Method of measurement
Questionnaire-Clinical File

6

Description
Duration of diagnosis
Timepoint
At The Beginning Of The Study
Method of measurement
Questionnaire-Clinical File

7

Description
The Stage Of Maturation Of The Patient
Timepoint
At The Beginning Of The Study
Method of measurement
Questionnaire-Clinical File

8

Description
Fasting Blood Sugar
Timepoint
At the beginning of the study, day 90 and day 180 in patients
Method of measurement
Paraclinic – Laboratory

9

Description
Hemoglobin A1C
Timepoint
At the beginning of the study, day 90 and day 180 in patients
Method of measurement
Paraclinic – Laboratory

10

Description
Triglyceride
Timepoint
At the beginning of the study, day 90 and day 180 in patients
Method of measurement
Paraclinic – Laboratory

11

Description
TYG index
Timepoint
At the beginning of the study, day 90 and day 180 in patients
Method of measurement
Paraclinic – Laboratory

12

Description
Insulin Carbohydrate Ratio
Timepoint
At the beginning of the study, day 90 and day 180 in patients
Method of measurement
Paraclinic – Laboratory

13

Description
Daily Use of Insulin
Timepoint
At the beginning of the study, day 90 and day 180 in patients
Method of measurement
Questionnaire-Clinical File

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: 180 capsules containing 500 mg cinnamon of Synabetic brand for using 2 times per day were provided to each patient in two 90 days courses, and the patients received supplements for 180 days in total.
Category
Treatment - Drugs

2

Description
The second intervention group: 90 tablets containing 200 microgram of chromium picolinate in VITABIOTICS brand for using once daily was provided to patients in two 90

days courses and the patients received supplements for 180 days in total.

Category

Treatment - Drugs

3

Description

Control group: With no intervention or placebo consumption and just with their insulin regime, control group were followed and evaluated the same as interventional groups in two 90 days courses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Shirin Ghane Fard

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Mofid Children's Hospital, Dr Shariati Ave.

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Sponsors / Funding sources

1

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Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shirin Ghane Fard

Position

Consulltant

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Other areas of specialty/work
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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
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
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 can potentially be shared after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
The data will be available to researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used
Unlimited

From where data/document is obtainable
Shirin Ghane Fard. 09123549408. Sh.ghanefard@sbmu.ac.ir.

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

Comments