

# 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 second group: 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

##### Email address

sh.ghanefard@sbm.ac.ir

##### 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 randomization. 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**

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**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****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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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**

Consultant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shadab Salehpour

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Shirin Ghane Fard  
**Position**  
Consultant  
**Latest degree**  
Subspecialist  
**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