

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of curcumin on glycemic control in children with type 1 diabetes

Protocol summary

Study aim

The effect of curcumin on glycemic control in children with type 1 diabetes

Design

triple blind parallel randomized controlled trial with control groups, phase 2, on 64 patients

Settings and conduct

Eligible children who referred to pediatric endocrine clinic, enter to this study. After gathering the demographic information, the duration of disease and the used drugs will be recorded in the checklist. Children will be randomized to two groups of intervention (use Curcumin tablet daily) and control (placebo). The nutritional healthy life style will be defined and advise to all participants. The duration of intervention will be 3 months. Fasting blood sugar will be assessed at baseline and monthly until 3 months. HbA1C and albuminuria will be assessed at baseline and after 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 7-18 year-old children, having type 1 diabetes, satisfied for participation in research project. Exclusion criteria: patients with systemic diseases like renal or hepatic failure, oral intolerance, not satisfied with continuation of the study.

Intervention groups

Intervention group: Curcumin tablet daily (contains 500 mg Curcumin and 5 mg Piperine) made by Sami-Sabinsa Group Limited. Placebo group: placebo (similar to intervention in shape, size and color) made by Sami-Sabinsa Group Limited.

Main outcome variables

Fasting blood sugar, HbA1C, Albuminuria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181022041407N3**

Registration date: **2023-06-17, 1402/03/27**

Registration timing: **prospective**

Last update: **2023-06-17, 1402/03/27**

Update count: **0**

Registration date

2023-06-17, 1402/03/27

Registrant information

Name

Maryam Emadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 9262

Email address

emadzadehm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin on glycemic control in children with type 1 diabetes

Public title

The effect of curcumin on type 1 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 7-18 years Having type 1 diabetes
Satisfaction for participation in research project

Exclusion criteria:
Patients with systemic diseases like renal or hepatic failure Oral intolerance of product Not satisfied with continuation of the study

Age
From **7 years** old to **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be done using the block sizes of 4 and 6 with randomization website (www.sealedenvelope.com). After randomization, the type of treatment will be written with A/B codes on separate papers and placed in an opaque envelope or the paper will wrap so that no one can see inside the paper (allocation concealment). After obtaining informed consent from the children and their parents, one paper will be taken in order and according to the noted code, the child will be placed in one of the intervention or placebo groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
As mentioned before, after randomization, the patients will be placed in two groups of A/B and will be received the products similar in shape, color and size (blinding of participants). The physician will received the boxes of the products with randomized codes (so the physician is blind too). The information of the patients and theirs treatment groups will be written with randomized codes (A/B) (the blinding of the assessor). Data will be entered to the SPSS software with codes (the blinding of the analyzer).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Mashhad University of Medical Sciences

Street address

Ghoreshi Building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2023-05-20, 1402/02/30

Ethics committee reference number

IR.MUMS.REC.1402.078

Health conditions studied

1

Description of health condition studied

Insulin-dependent diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar (FBS)

Timepoint

baseline and monthly for 3 months

Method of measurement

blood sample

2

Description

HbA1C

Timepoint

baseline, after 3 months

Method of measurement

blood sample

Secondary outcomes

1

Description

microalbuminuria

Timepoint

baseline and after 3 months

Method of measurement

urine analysis

Intervention groups

1

Description

Intervention group: Curcumin tablet daily (contains 500 mg Curcumin and 5 mg Piperine) made by Sami-Sabinsa Group Limited, for 90 days

Category

Treatment - Drugs

2

Description

Control group: placebo (microcrystalline cellulose) made by Sami-Sabinsa Group Limited, for 90 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric endocrinology clinic

Full name of responsible person

Somayyeh Hashemian

Street address

between 1st and 3rd Besat, Besat Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-Mobarhan

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vcresearch@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/>

Grant name

Grant code / Reference number

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

Maryam Emadzadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Somayyeh Hashemian

Position

non-academic staff

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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

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

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

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

Data Dictionary

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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Emadzadeh

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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