Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3841 0000
Email
hashemians951@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan
Street address
Ghoreshi Building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email
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
Street address
Clinical Research Development Unit, Ghaem Hospital, Ahmadabad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3841 7403
Email
maryamemadzadeh@yahoo.com

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
Street address
between 1st and 3rd Besat, Besat Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3841 0000
Email
hashemians951@gmail.com

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
Specialist
Other areas of specialty/work
Public Health/Community Medicine
Street address
Clinical Research Development Unit, Ghaem Hospital, Ahmadabad Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3841 7403
Email
maryamemadzadeh@yahoo.com

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