

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of medlar fruit molasses (*Mespilus germanica L.*) on blood glucose control in children and adolescents with type 1 diabetes - A randomized clinical trial

#### Protocol summary

##### Study aim

Due to the traditional use of Medlar fruit molasses as hypoglycemic agent, the aim of this study is to evaluate the effectiveness of medlar molasses in controlling blood sugar in patients with type 1 diabetes.

##### Design

This study was designed as a crossover randomized clinical trial using the intention to treat approach in consecutive diabetic children referred to the diabetes clinic of Bu-Ali sina Hospital. Patients who met the inclusion criteria were randomly divided into two groups : A (medlar molasses + insulin) and B (insulin) by using a computer program to generate random numbers.

##### Settings and conduct

Crossover randomized clinical trial in diabetic children referred to the diabetes clinic of Bu-Ali Sina Hospital.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The age group of patients is between 5-18 years. Children and adolescents with poorly controlled type 1 diabetes ( $HbA1c \geq 8$ ). The consent of the patient and parents to participate in the study has been obtained. Exclusion criteria: Patients with syndromic disorders (such as Down syndrome, etc.) Presence of renal failure in the patient ( $GFR < 30$ ) Taking drugs that affect blood sugar levels (lowering blood sugar such as metformin and raising blood sugar such as corticosteroids)

##### Intervention groups

After randomization, in the first 45 days, group A receives a certain amount of medlar fruit molasses (the dose is determined based on the total phenol content of the product) along with the required dose of insulin, and group B, only with insulin treatment. In the second 45-day period, the two groups will be swapped

##### Main outcome variables

C-Peptide, HbA1c

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160913029802N3**

Registration date: **2021-12-07, 1400/09/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-07, 1400/09/16**

Update count: **0**

##### Registration date

2021-12-07, 1400/09/16

##### Registrant information

##### Name

Somayeh Shahani

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3354 3761

##### Email address

s.shahani@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-11, 1400/08/20

##### Expected recruitment end date

2022-05-10, 1401/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of the effect of medlar fruit molasses (Mespilus germanica L.) on blood glucose control in children and adolescents with type 1 diabetes - A randomized clinical trial

### Public title

Evaluation of the effect of medlar fruit molasses on blood glucose control in children and adolescents with type 1 diabetes

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

The age group of patients is between 5-18 years. Children and adolescents with poorly controlled type 1 diabetes (HbA1c $\geq$ 8). The consent of the patient and parents to participate in the study has been obtained.

#### Exclusion criteria:

Patients with syndromic disorders (such as Down syndrome, etc.) Presence of renal failure in the patient (GFR <30) Taking drugs that affect blood sugar levels (lowering blood sugar such as metformin and raising blood sugar such as corticosteroids)

### Age

From **5 years** old to **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, we will use the restricted randomization method (the blocked randomization) using Random Allocation Software. The size of all blocks is equal and in this trial, we will have five blocks of 6 (including 3 participants in group A and 3 participants in group B). Each patient will receive a unique code and the software will randomly place the patients in groups A or B, depending on the sample size in each block.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Crossover

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

##### Street address

Vice Chancellor for Research and Technology, Moallem Square

##### City

Sari

##### Province

Mazandaran

##### Postal code

33971- 48157

#### Approval date

2021-09-29, 1400/07/07

#### Ethics committee reference number

IR.MAZUMS.REC.1400.477

## Health conditions studied

### 1

#### Description of health condition studied

Type 1 diabetes

#### ICD-10 code

E10

#### ICD-10 code description

Type 1 diabetes mellitus

## Primary outcomes

### 1

#### Description

C-Peptide

#### Timepoint

To determine the level of C-Peptide in patients, a blood sample is taken from the patient on an empty stomach and at intervals of 30, 60, 90 and 120 minutes after consuming a mixture of liquid (containing 50% carbohydrates, 30% fat and 20% protein with a standard concentration of 6 ml per kg, up to 360 ml).

#### Method of measurement

ELIZA Reader

### 2

#### Description

HbA1c

#### Timepoint

HbA1c (using Biroex kit) is measured at the beginning of the study, day 45 (group switching time) and the end of the study, in the laboratory of Bu-Ali Sina Hospital in Sari.

#### Method of measurement

Hemoglobin A1c analyzer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group A: After randomization allocation, in the first 45 days, group A receives a certain amount of medlar fruit molasses (the dose is determined based on the total phenol content of the product) along with the required dose of insulin. The wash out period is two weeks, during which patients do not receive any intervention other than insulin injection. During the second 45-day period, this group will receive only the insulin they need. Patient demographic information including age, sex, height and weight as well as HbA1c levels are measured at the beginning of the study, day 45 (time of group switching) and the end of the study.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group B: After randomization allocation, in the first 45 days, this group will receive only the insulin they need. Then the wash out period is two weeks and during this period patients do not receive any intervention except insulin injection. In the second 45-day period, group B receives a certain amount of medlar fruit molasses (the dose is determined based on the total phenol content of the product) along with the required dose of insulin. Patient demographic information including age, sex, height and weight as well as HbA1c levels are measured at the beginning of the study, day 45 (time of group switching) and the end of the study.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Bu-Ali Sina Hospital

##### Full name of responsible person

Dr Daniel Zamanfar

##### Street address

Bu-Ali Sina Hospital , Sari, Mazandaran, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

۴۸۱۵۸۳۸۴۷۷

##### Phone

+98 11 3334 5601

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr Majid Saeedi

##### Street address

Research and Technology Deputy, Moallem square

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##### Province

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4815733971

##### Phone

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msaeedi@mazums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Vice chancellor for research and technology, Mazandaran 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Somayeh Shahani

##### Position

Assistant Professor, Department of Pharmacognosy and Biotechnology

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

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Faculty of Pharmacy, Mazandaran University of Medical Sciences, Km 18 of Khazarabad Road

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Latest degree**  
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**Web page address**

## 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 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