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≥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≥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

Email
dzamanfar@mazums.ac.ir

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

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3325 7230

Email
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

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

City
Sari

Province
Mazandaran
Postal code
48471-93698
Phone
+98 11 3354 3761
Email
so.shahani@yahoo.com

Person responsible for scientific 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
Street address
Faculty of Pharmacy, Mazandaran University of Medical Sciences, Km 18 of Khazarabad Road
City
Sari
Province
Mazandaran
Postal code
48471-93698
Phone
+98 11 3354 3761
Fax
Email
so.shahani@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Faculty of Pharmacy, Mazandaran University of Medical Sciences, Km 18 of Khazarabad Road
City
Sari
Province
Mazandaran
Postal code
48471-93698
Phone
+98 11 3354 3761
Fax
Email
so.shahani@yahoo.com
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