Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of a newly designed natural sweetener (Lacritose) compared to sucrose and glucose on blood glucose concentrations and possible gastrointestinal reactions in patients with type 2 diabetes: a double-blind randomized three way cross-over clinical trial

Protocol summary

Summary

Aims and design: The present study will explore the effect of the sweetener Lacritose compared with sucrose and glucose in patients with type 2 diabetes. This study will be a double-blind three way cross-over clinical trial on type 2 diabetic patients. All the participants (n=20) will undergo three treatment periods (Lacritose, sucrose and glucose) to examine their effect on blood sugar. Sweeteners and their solution in tap water are completely the same.The sweeteners will be marked as A, B and C by a person who is not aware of study objectives and protocols in order to blind both participants and investigators. Then the sweeteners will be dissolved in 300 ml of tap water and the beverages will be ingested by participants. Methods: After filling demographic questionnaire height will be measured without shoes by a tape measure fixed on a wall, with 1 centimeter accuracy and weight will be measured by a digital scale with 100 gram accuracy. All participants will randomly ingest the test beverages (Lacritose, sucrose or glucose beverage) when they are in a fasted state on the intervention days. There will be six days as washout period between ingesting each test beverage. Participants will be asked to come to laboratory while they are fasted overnight for 8-12 hours on the intervention days and then they will give blood sample to measure fasting blood sugar levels. 5 ml of blood sample will be taken from each participant to assess the fasting blood sugar levels. Then the test powders (50 grams of Lacritose, sucrose or glucose) will be given to participants dissolved in 300 ml of tap water. The participants will be asked not to ingest any meals, tea, coffee, smoke or drugs and avoid intense physical activity up to 2 hours after drinking the test drinks. Outcome measurement: Subjects will give blood samples every 30 minutes after drinking the test solutions up to 2 hours on blood sugar increase. The gastrointestinal adverse reactions to the sugars will also be checked up to 24 hours after ingesting each test beverage.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050912571N2**
Registration date: **2016-09-15, 1395/06/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-15, 1395/06/25

Registrant information

Name

Amin Salehi-Abargouei

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

Email address

abargouei@hlth.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date
2016-10-21, 1395/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of a newly designed natural sweetener (Lacritose) compared to sucrose and glucose on blood glucose concentrations and possible gastrointestinal reactions in patients with type 2 diabetes: a double-blind randomized three way cross-over clinical trial

Public title
The safety and effect of a new sweetener (Lacritose) compared to sugar and glucose on postprandial blood sugar
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Type 2 diabetic patients (n=20) with fasting blood sugar >125 mg/dl and lower than 200 mg/dl, aged 20 to 60. Exclusion criteria: Participants will not be included in the trial if they were pregnant or lactating, had severe infection, endocrine disorders or acute diseases at the enrollment. Participants who intend to exit with any reasons or show any adverse reaction to test sugars will also be excluded from the study. .
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features
Randomization: All Participants will randomly ingest the three intervention beverages [consisting of 50 gram of test sugars (lacritose, sucrose and glucose) and tap water] coded as A, B or C, for one time. The order of ingesting the test beverages (rolling methods) will be randomized by computer using statistical package for social sciences (SPSS) software version 15. Participants will be randomized into 6 rolling methods (ABC, ACB, BCA, BAC, CAB, and CBA). The random order will be written on a paper and will be kept in opaque envelopes and after presence of subjects in laboratory, the pocket will be opened and the order of ingesting beverages will be revealed for the study team.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Shahid Sadoughi University of Medical Sciences
Street address
Faculty of Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
City
Yazd
Postal code
Approval date
2015-07-01, 1394/04/10
Ethics committee reference number
IR.SSU.SPH.REC.1394.31

Health conditions studied

1

Description of health condition studied
Non-insulin-dependent diabetes mellitus
ICD-10 code
E11
ICD-10 code description
non insulin dependent diabetes mellitus

Primary outcomes

1

Description
Postprandial blood sugar
Timepoint
Every 30 minutes up to 2 hours after ingesting the test beverages
Method of measurement
Using pars azmoon kits using automated azalyzer

Secondary outcomes

1

Description
Gastrointestinal symptoms
Timepoint
24 hour after ingesting the test beverages
Method of measurement
Gastrointestinal symptoms questionnaire

Intervention groups

1

Description
50 grams of Lacritose dissolved in 300 ml of tap water
Category
Treatment - Drugs

2

Description
50 grams of sucrose dissolved in 300 ml of tap water
Category
Placebo

3

Description
50 grams of glucose dissolved in 300 ml of tap water
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghaei pour obesity clinic, Shahid sadoughi University of Medical Sciences, Yazd, Iran
Full name of responsible person
Street address
Baghaei pour obesity clinic, Shahid sadoughi University of Medical Sciences, Yazd, Iran
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Sadoughi University of Mecical Sciences
Full name of responsible person
Dr. Amirhushang Mehrparvar
Street address
Vice-chancellery for research and technology, Shahid Sadoughi University of Medical Sciences, Bahonar Square, Yazd, Iran.
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahid Sadoughi University of Mecical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr. Amirhoushang Mehrparvar
Position
Vice chancellor for research, Shahid Sadoughi University of Medical Sciences
Other areas of specialty/work
Street address
Vice-chancellary for research and technology, Shahid Sadoughi University of Medical Sciences, bahonar Square, Yazd, Iran
City
Yazd
Postal code
Phone
+98 35 3726 6711
Fax
Email
ah.mehrparvar@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nutrition and Food Security Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, I
Full name of responsible person
Dr. Amin Salehi-Abargouei
Position
PhD
Other areas of specialty/work
Street address
Department of Nutrition, Faculty of Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran
City
Yazd
Postal code
Phone
+98 35 3820 9100
Fax
Email
abargouei@gmail.com; abargouei@hlth.mui.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Nutrition and Food Security Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, I

Full name of responsible person
Mohammad Ali Mohsenpour

Position
BSc in Nutrition, MSc Student

Other areas of specialty/work

Street address
Department of Nutrition, International Campus, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

City
Yazd

Postal code

Phone
+98 35 3820 9100

Fax

Email
mohammadali.mohsenpour@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty