Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of average blood sugar in people with type II diabetes natural sweetener consumers Lacriroze and control group-clinical trial

Protocol summary

Summary

This study was designed as a randomized, randomized clinical trial. Patients will be selected by targeted sampling according to the inclusion and exclusion criteria from patients referred to Yazd Diabetes Therapy Research Center. Patients entered into the study by randomized blocking method are divided into 3 groups (two intervention groups and one control group). Each of the three groups is under diabetic regimen for 2 weeks. Their blood indices are then measured. The maximum daily dose of sucrose (normal sugar) is calculated for the diabetic patient in grams per kilogram by a nutritionist. To the first group (control) only sucrose is given, the second group (first intervention) half the dose of sucrose is reduced, instead of its equivalent, lacrithosis is given, and the third group (second intervention) only lacrithosis is set at the maximum dose of sucrose to gram / Kilograms.In fact, in this study, none of the patients received any sweetener than the dose of sucrose. Patients will continue to receive their diabetes during two weeks, and they will be contacted every three days, asking questions about the use of sweetener, possible complications, and compliance with the diabetic diet. The total number of patients studied is 30, which is determined for each group of 10 people. The trainer will be trained on how to ask patients and complete the questionnaire. It should be noted that the study is done in 3 blind corners. A dietitian recommends the same diabetic diet to all patients without knowing which patients belong to.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102418858N7**
Registration date: **2017-11-13, 1396/08/22**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-11-13, 1396/08/22

Registrant information

Name
Masoud Rahmanian
Name of organization / entity
Diabet Research Center, Yazd Shahid Sadughi University Of Mdical Science
Country
Iran (Islamic Republic of)
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+98 35 1728 0215
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rahmanian@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Reza Nazemian

Expected recruitment start date

2017-11-06, 1396/08/15

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of average blood sugar in people with type II diabetes natural sweetener consumers Lacriroze and control group-clinical trial

Public title

The effect of natural sweetener lacrithosis on blood glucose in type 2 diabetic patients

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Type 2 diabetes, the age group of 30-60, fasting blood glucose less than 200 mg / dl, HbA1C≤9≥7, are under the control of oral hypoglycemic or dietary medications, are not treated with insulin. Sugar in the diet of the patient. Drugs for blood sugar, blood lipids and blood pressure did not change during the past month, having a medical record at the Yazd diabetes research center, a willingness to participate in research. Exclusion criteria: Patient's inability to follow-up (life in the city, end stage, patients who need to control high blood sugar due to complications of diabetes, those who have a severe change in their calories and their activity, people with deficiency of Lactose, pregnancy And lactation, patients with severe infections or endocrine disorders, those with acute illnesses, people with liver and kidney failure, patients with diabetes complications (nephropathy, neuropathy, retinopathy), BMI≥35
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd University of Medical Science
Street address
Bahonar square, Yazd, Iran
City
Yazd
Postal code
8917693571
Approval date
2017-08-15, 1396/05/24
Ethics committee reference number
IR.SSU.REC.1396.102

Health conditions studied

1

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

Primary outcomes

1

Description
FBS
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

2

Description
2hPP
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

3

Description
Fructosamine
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

4

Description
Insulin
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

5

Description
Urea
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

6

Description
Cr
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

7

Description
SGOT
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

8

Description
SGPT
Timepoint
Before the intervention, After the intervention
Method of measurement
Blood Test

Secondary outcomes

1

Description
BMI
Timepoint
Before the intervention, After the intervention
Method of measurement
Balance and meter

2

Description
Digestive complications
Timepoint
Before the intervention, After the intervention
Method of measurement
Questionare

Intervention groups

1

Description
Sucrose and Lacritoze
Category
Lifestyle

2

Description
Lacritoze
Category
Lifestyle

3

Description
Sucrose
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabete Research Center
Full name of responsible person
Masoud Rahmanian
Street address
Talar Honar alley, Bahonar square, Yazd, Iran
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Medical Sciences and Health Services, Yazd
Full name of responsible person
Reza Nazemian
Street address
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
University of Medical Sciences and Health Services, Yazd
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
Yazd University of Medical Science
Full name of responsible person
Mozhghan Modarresi
Position

Community Medicine Specialist

Other areas of specialty/work

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Iran, Yazd, Diabete Research Center

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Science

Full name of responsible person

Reza Nazemian

Position

Dentist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Science

Full name of responsible person

Fariba Sepehri

Position

Researcher, MA

Other areas of specialty/work

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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