

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effects of oral trehalose supplementation on glycemic control in patients with type 2 diabetes

Protocol summary

Study aim

The aim of this study is to determine the effectiveness of trehalose on reducing glycemic indices in patients with diabetes type 2

Design

This study has been designed as a randomized, triple-blind, placebo-controlled and parallel trial.

Settings and conduct

A total of 40 enrolled patients will be divided into two treatment and control groups (trehalose and sucrose). Patients will be instructed to ingest the preparation (1.65 g twice a day), approximately 3.3 g/day for 3 months (trehalose n=20, placebo n=20). The participants were permitted to prepare the substances for consumption in a variety of ways, such as dissolving them in beverages. Ghaem Hospital/ Faculty of Medicine/ Faculty of pharmacy

Participants/Inclusion and exclusion criteria

Inclusion criteria: 40 patients (male or female) with non-insulin-dependent diabetes (HbA1C 7-9%) having stable condition Exclusion Criteria: Patients with any type of insulin-dependent diabetes receiving insulin therapy (also patients participating will be excluded from the study if they need insulin) Patients with renal dysfunction (eGFR less than 30 ml/min) Patients with severe liver dysfunction or cirrhosis. Patients regularly receiving oral or injectable corticosteroids or those who used α -Glucosidase Inhibitors such as acarbose. Patients who were pregnant or nursing or wished to conceive.

Intervention groups

Patients will be randomly divided into two treatment and control groups, which will be received trehalose and sucrose as intervention/placebo groups, respectively. Enrolled patients will be instructed to ingest the preparation in opaque sachet form (1.65 g twice a day) for 3 months (trehalose n=20, placebo n=20).

Main outcome variables

The primary endpoint: changes in HOMA-IR as an index of insulin resistance. Secondary endpoints include

changes in fasting plasma glucose (FPG), insulin, HbA1c, C-peptide and hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130829014521N18**

Registration date: **2021-03-16, 1399/12/26**

Registration timing: **prospective**

Last update: **2021-03-16, 1399/12/26**

Update count: **0**

Registration date

2021-03-16, 1399/12/26

Registrant information

Name

Amirhossein Sahebkar

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1882 9260

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation of the effects of oral trehalose supplementation on glycemic control in patients with type 2 diabetes

Public title
Trehalose and diabetes type 2

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Male or female patients aged between 35 and 85 years
Patients with non-insulin-dependent diabetes mellitus in a stable condition.
Exclusion criteria:
Patients with type 1, type 2, or secondary diabetes receiving insulin therapy. Patients with renal dysfunction (eGFR less than 30 ml/min). Patients with severe liver dysfunction or cirrhosis. Patients regularly receiving oral or injectable corticosteroids. Patients who were pregnant or nursing or wished to conceive. Patients participating in this study will be excluded from the study if they need insulin. Patients who used α -Glucosidase Inhibitors such as acarbose will be excluded from the study.

Age
From **35 years** old to **85 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
This study has been designed as a randomized, triple-blind, placebo-controlled and parallel trial. Simple randomization for allocation and sealed envelope approach would be considered for concealed allocation.

Blinding (investigator's opinion)
Triple blinded

Blinding description
This study has been designed as triple-blind and persons including participants, care providers, investigators, and outcome assessors, keeping unaware of the treatment administered, moreover, drug and placebo vials have similar packaging and labeling.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of National institute for medical research development

Street address

No. 21, west Fatemi Ave, Besat Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1419693111

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.NIMAD.REC.1399.267

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11. 9

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

HOMA-IR alterations

Timepoint

At the beginning and end of the intervention trial (Day 0 and week 12)

Method of measurement

HOMA-IR = fasting insulin (microU/L) x fasting glucose (nmol/L)/22.5

Secondary outcomes

1

Description

fasting plasma glucose (FPG)

Timepoint

Baseline and week 12

Method of measurement

Enzymatic assay

2

Description

Fasting insulin

Timepoint

Baseline and week 12

Method of measurement

Immunoassay

3

Description

HbA1c

Timepoint

Baseline and week 12

Method of measurement

chromatography

4

Description

C peptide

Timepoint

Baseline and week 12

Method of measurement

Immunoassay

5

Description

hs-CRP

Timepoint

Baseline and week 12

Method of measurement

Turbidimetric

Intervention groups

1

Description

Intervention group: Terhalose (natural disaccharide), 1.65 g twice a day (3.3 g/day) for 3 months, in opaque sachet form

Category

Treatment - Drugs

2

Description

Control group: Sucrose, 1.65 g twice a day (3.3 g/day) for 3 months, in opaque sachet form

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mohammad Ali Yaghoubi

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Ahmadabad Blvd, Mashhad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development

Full name of responsible person

Dr. Reza Malekzadeh

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NIMAD@RESEARCH.AC.IR

Grant name

Grant code / Reference number

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

Yes

Title of funding source

National Institute for Medical Research Development

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Amirhossein Sahebkar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of Pharmacy, East door of Ferdowsi University,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Associate professor

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available