Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of type of pre-exercise breakfast on postprandial glycemic indices in women with type 2 diabetes

Protocol summary

Study aim

Investigating the effect of fasting and the type of breakfast before exercise on the index of the area under the glucose curve after a meal (Glucose AUC) and glucose levels 2 hours after a meal in women with type 2 diabetes

Design

Clinical trial with crossover groups, unblinded, randomized, on 12 patients ,Simple randomization

Settings and conduct

This research is of a semi-experimental and cross-over type, in which the subjects will randomly perform one of the following 4 interventions with an interval of one week:1- Exercise while fasting,2- Exercise after consuming a standard breakfast ,3- Exercise after consuming breakfast with high carbohydrates and low protein ,4- Exercise after Eating breakfast with high protein and low carbohydrates. In the first intervention, people will perform the specified exercise in fasting state and 10 minutes later, a glucose tolerance test will be taken. In the second, third, and fourth interventions, the subjects will perform exercise 90 minutes after consuming the indicated breakfast, and a glucose tolerance test will be taken 10 minutes after the exercise.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having type 2 diabetes, being allowed to engage in physical activity, not having a history of regular sports activity, no change in diet and medication. Exclusion criteria: suffering from knee osteoarthritis, use of insulin in the treatment process, suffering from cardiovascular disease, male gender

Intervention groups

1: performing sports activities while fasting 2: Doing sports activities after eating a standard breakfast 3: doing sports activities after eating breakfast with high protein 4: doing sports activities after consuming breakfast with high carbohydrates

Main outcome variables

Index of the area under the glucose curve after a meal (AUC Glucose); Glucose levels 2 hours after a meal

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231108060000N1**
Registration date: **2023-12-29, 1402/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-29, 1402/10/08**
Update count: **0**

Registration date

2023-12-29, 1402/10/08

Registrant information

Name
Mona Emandost
Name of organization / entity
The university of kashan
Country
Iran (Islamic Republic of)
Phone
+98 31 5557 0700
Email address
monaimandust@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-27, 1402/10/06

Expected recruitment end date

2024-01-15, 1402/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of type of pre-exercise breakfast on postprandial glycemic indices in women with type 2 diabetes

Public title

The effect of fasting and the type of pre-exercise on diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

At least six months have passed since the diagnosis of type 2 diabetes by the relevant doctor not changing the diet and medication not having a history of exercising regularly being allowed to exercise

Exclusion criteria:

Having knee osteoarthritis Having cardiovascular disease Male gender Using insulin in the treatment process

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects included in the current research will implement one of the four interventions in a cross-over manner with a random design. To randomize the interventions, the method of simple randomization using sealed envelopes will be used. Also, the person who will group the interventions will be blinded to the type of intervention.

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

Research ethics committees of kashan university

Street address

Sedaghat allry, shahid gholi Ave ,shahid beheshti Ave , kashan Toen

City

Kashan

Province

Isfehan

Postal code

8715145333

Approval date

2023-11-06, 1402/08/15

Ethics committee reference number

IR.KASHANU.REC.1402.041

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Blood glucose

Timepoint

15 minutes; 30 minutes; 60 minutes; 90 minutes; 120 minutes after exercise

Method of measurement

Glocometere

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: People eat a standard breakfast with a certain combination of macronutrients, including 55 grams of carbohydrates, 15 grams of protein, and 30 grams of fat. After one hour, they perform specific exercise and their blood glucose levels are measured at specific time intervals.

Category

N/A

2

Description

Intervention group: People eat breakfast with high carbohydrates including 55 grams of carbohydrates, 22 grams of protein, and 13 grams of fat. After one hour,

they perform specific exercise and their blood glucose levels are measured at specific time intervals.

Category

N/A

3

Description

Intervention group: People eat breakfast with high protein including 22 grams of carbohydrates, 55 grams of protein, and 13 grams of fat. After one hour, they perform specific exercise and their blood glucose levels are measured at specific time intervals.

Category

N/A

4

Description

Control group: People perform specific sports training while fasting and their blood glucose levels are measured during specific time intervals.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

diabetes association

Full name of responsible person

Mona Emandost

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sedaghat Alley- Gholi ave - Beheshti Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan university

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan university

Proportion provided by this source

10

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

Kashan university

Full name of responsible person

Mona Emandost

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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Person responsible for updating data

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable