Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

The effect of anti-inflammatory, portfolio low carbohydrate, and intermittent fasting on cardio- metabolic status and gene expression in subject with pre-diabetes; an open label randomized clinical trial

Protocol summary

Study aim

The effect of anti-inflammatory diets, low carbohydrate portfolio and intermittent fasting on cardiometabolic status and gene expression

Design

The clinical trial has a control group with randomized and open label on 100 patients with pre-diabetes, which will be used for randomization from the table of random numbers.

Settings and conduct

In order to carry out the present study, by examining the files of patients referred to the central laboratory of Kermanshah University of Medical Sciences, patients who meet the conditions to enter the study will be invited to the laboratory of the School of Nutritional Sciences and Food Technology

Participants/Inclusion and exclusion criteria

A total 100 patients with pre-diabetes will be invited according to ADA criteria, aged 18-55 years and BMI ≥25 kg/m2, who consented to participate in the study. Conditions for not including to the study as follow: pregnancy, lactation, suffering from diseases such as autoimmune diseases, thyroid and unstable cardiovascular diseases, diabetes, severe depression (due to the inability to answer the questions)), mental and mental illnesses, and finally medication use related to the above conditions. patients who refuse to cooperate during the intervention, patients who become unavailable due to migration or any other reason, women who become pregnant during the intervention will be excluded from the study.

Intervention groups

Participants were randomly divided into 4 groups: 1) calorie restriction (control) (n=25), 2) low carbohydrate portfolio diet group (n=25), 3) intermittent fasting group (n=25) and 4) group anti-inflammatory diet (n=25) will be divided.

Main outcome variables

Improving glycemic indices and related gene expression including insulin Receptor (INSR), transcription factor 7 like 2 (TCF7L2), PPARG Co-activator 1- α (PGC1-a)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047697N2**
Registration date: **2024-05-16, 1403/02/27**
Registration timing: **prospective**

Last update: **2024-05-16, 1403/02/27**
Update count: **0**

Registration date

2024-05-16, 1403/02/27

Registrant information

Name

Shima Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2015

Email address

shima.moradi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of anti-inflammatory, portfolio low carbohydrate, and intermittent fasting on cardio-metabolic status and gene expression in subject with pre-diabetes; an open label randomized clinical trial

Public title

Investigating effect of anti-inflammatory, portfolio low carbohydrate, and intermittent fasting on improving pre-diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-55 years BMI ≥25 kg/m2 Consent to participate in the study Suffering from pre-diabetes according to ADA criteria (hemoglobin A1c level between 5.7 and 6.4% or FBS level between 100-125 mg/dL)

Exclusion criteria:

Pregnancy and lactation Suffering from diseases such as autoimmune diseases, thyroid and unstable cardiovascular diseases, diabetes, severe depression (due to the inability to answer questions), mental and psychological diseases Medication use related to the above conditions

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly divided into 4 groups using a random number table: 1) calorie restriction (control) (n=25), 2) low carbohydrate portfolio diet group (n=25), 3) intermittent fasting group (n= 25) and 4) the anti-inflammatory diet group (n=25).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah Province, Kermanshah, Beheshti Blvd, 83VX+PCM

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2024-04-23, 1403/02/04

Ethics committee reference number

IR.KUMS.REC.1403.045

Health conditions studied

1

Description of health condition studied

pre- diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improving glycemic indices and related gene expression including insulin Receptor (INSR), transcription factor 7 like 2 (TCF7L2), PPARG Co-activator 1- α (PGC1-a)

Timepoint

All measurements will be done at the beginning of the study (before the intervention) and at the end of the study (after the intervention).

Method of measurement

Glycemic indices including insulin level, blood sugar, hemoglobin A1c will be evaluated in the central laboratory of the University of Medical Sciences. The expression of the mentioned genes is determined by Real Time PCR method and specific primers designed with reliable software.

Secondary outcomes

1

Description

Anthropometric indices and body composition

Timepoint

Before the intervention, in the middle of the study (end of week 6), after the intervention

Method of measurement

Anthropometric measurements include height, weight, waist circumference. Height will be measured in a standing position without shoes. Measurement of waist circumference in the narrowest area, the distance between the bottom of the last rib and the top of the pubic bone in exhalation, is done using an inflexible tape measure without bearing any pressure on the person's body with an accuracy of 0.1 cm. Accurate assessment of weight and body composition is done by the body composition analysis device (Jawon Medical Plus model Avis 333) available in the research laboratory of the school of Nutritional Sciences and Food Technology. Body mass index (BMI) will be calculated by dividing weight (kilograms) by the square of height (meters).

2

Description
blood pressure
Timepoint
Before the intervention, in the middle of the study (end of week 6), after the intervention
Method of measurement
A digital arm sphygmomanometer will be used to measure people's blood pressure. At least half an hour before, people should not have intense activity, they should not have consumed coffee, tea and cigarettes. For this purpose, the participant will be asked to sit on an armchair for 5 minutes before the measurement. Then we will measure the person's blood pressure from the left arm twice at 15 minutes intervals. Finally, we will record the average blood pressure measured.

3

Description
C reactive protein
Timepoint
before and after intervention
Method of measurement
It will be evaluated by the central laboratory of Kermanshah University of Medical Sciences.

4

Description
lipid profile
Timepoint
before and after intervention
Method of measurement
It will be evaluated by the central laboratory of Kermanshah University of Medical Sciences.

Intervention groups

1

Description
Intervention group: anti-inflammatory diet- Diet characteristics: 1. Restriction of daily calorie intake (75% of daily energy requirement). 2. Variety with sufficient amounts of fresh foods, minimum amount of processed foods and fast foods, 3. Abundant amounts of fruits and vegetables with a limit on daily calorie intake - The desired diet is provided to patients in the form of a meal plan along with nutrition counseling every month. .
Category
Prevention

2

Description
Intervention group: portfolio low carbohydrate diet- Diet characteristics: this diet emphasizes 4 components: soluble fiber, nuts, soybeans, and fatty acids with a double bond (MUFA), which distribution of macronutrients is as follows: 40% fat, carbohydrates 40%, 20% protein, daily calorie restriction - The desired diet is provided to patients in the form of a meal plan along with nutrition counseling every month.
Category
Prevention

3

Description
Intervention group: intermittent fasting diet- Diet characteristics: 5:2 diet, 2 days a week: 500 to 600 kcal per day (breakfast 100 kcal, lunch and dinner 250 kcal each) - 5 days a week: 2000 kcal - The desired diet is provided to patients in the form of a meal plan along with nutrition counseling every month.
Category
Prevention

4

Description
Control group: Calorie restriction diet- Diet characteristics: restriction of daily calorie intake (75% of daily energy requirement) and carbohydrate distribution: breakfast: 15%, snack: 13%, lunch: 24%, snack: 13%, dinner: 24%, late night: 11% - The desired diet is provided to patients in the form of a meal plan along with nutrition counseling every month.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
central laboratory of Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Nayeb Ali Rezvani
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http://www.referencelab.ir/Main/MainPage.aspx

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr Sirus Jalili
Street address
Kermanshah - Shahid Beheshti Boulevard - Central Building of Kermanshah University of Medical Sciences
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Email
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Web page address
https://vc-research.kums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Shima Moradi
Position
PhD Student
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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6719851552

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shima.moradi1400@yahoo.com

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
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Data collected for the primary outcomes will be shared.

When the data will become available and for how long
After publication of the results in valuable Journals

To whom data/document is available
The data will only be available for people working in academic institutions.

Under which criteria data/document could be used
For Meta- analysis studies

From where data/document is obtainable
Shima Moradi- Shool of nutritional Sciences and Food Technology Shima.Moradi@kums.ac.ir

What processes are involved for a request to access data/document
By email Shima.Moradi@kums.ac.ir

Comments