

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of gluten free diet effect on anthropometric measurements, metabolic syndrome's determinants, insulin resistance, inflammatory factors , gut flora in patients with metabolic syndrome

Protocol summary

Study aim

Assessment of gluten free diet effect on anthropometric measurements, metabolic syndrome's determinants, insulin resistance, inflammatory factors , gut flora in patients with metabolic syndrome

Design

In this randomized clinical trial, 46 subjects diagnosed with metabolic syndrome according to the Adult Treatment Panel III (ATP III) criteria were recruited and a code was allocated to each one of them. Patients were randomly divided into two control and intervention groups.

Settings and conduct

We selected eligible patients based on inclusion criteria from Nutrition and diet therapy clinic, Shahid Beheshti University of Medical Sciences and randomly assigned them into two intervention (n = 23) or control group (n = 23)

Participants/Inclusion and exclusion criteria

Inclusion criteria: having at least three of the dimensions of metabolic syndrome, including weight circumference $\geq$ 95cm for both genders, high blood pressure (systolic blood pressure $\geq$ 130mmHg and diastolic blood pressure $\geq$ 85mmHg) and high triglyceride (>150 mg/dL) Age range 25-65 years BMI $\geq$ 25kg/m²
Exclusion criteria: using fat burning and weight loss drugs, multivitamin/mineral, omega-3 and green tea supplements in the past month using insulin or drugs (Metformin or Glibenclamide) for controlling blood sugar having thyroid gland disorders Pregnancy and Lactation ,athletics

Intervention groups

The intervention group received the GFD diet and the control group were informed to continue their regular diet for eight weeks. In the GFD diet, patients were assumed to receive less than 2-gram gluten per day. Through the intervention process, individuals received

gluten free breads. Additionally, participants were informed to not use other cereals containing gluten such as cakes, biscuits and etc

Main outcome variables

Fasting blood glucose Triglyceride Cholesterol High Density Lipoprotein (HDL) Low Density Lipoprotein(LDL) Insulin Homeostasis model assessment for insulin resistance (HOMA-IR) Body weight Waist circumference Systolic and Diastolic pressure Intestinal microbiom C Reactive Protein(CRP) Tumor necrosis factor alpha(TNF- α) Interleukin 6(IL-6)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170723035244N1**
Registration date: **2018-01-07, 1396/10/17**
Registration timing: **retrospective**

Last update: **2018-01-07, 1396/10/17**

Update count: **0**

Registration date

2018-01-07, 1396/10/17

Registrant information

Name

mehdi ehteshami

Name of organization / entity

National Nutrition and Food Sciences Technology
Research Institute

Country

Iran (Islamic Republic of)

Phone

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Recruitment status**Recruitment complete****Funding source**National Nutrition and Food Sciences Technology
Research Institute**Expected recruitment start date**

2016-08-22, 1395/06/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

2016-08-22, 1395/06/01

Actual recruitment end date

2017-02-19, 1395/12/01

Trial completion date

empty

Scientific title

Assessment of gluten free diet effect on anthropometric measurements, metabolic syndrome's determinants, insulin resistance, inflammatory factors , gut flora in patients with metabolic syndrome

Public title

The effects of gluten free diet on patients with metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**having at least three of the dimensions of metabolic syndrome, including weight circumference $\geq$ 95cm for both genders, high blood pressure (systolic blood pressure $\geq$ 130mmHg and diastolic blood pressure $\geq$ 85mmHg) and high triglyceride (>150 mg/dL) Age range 25-65 years BMI $\geq$ 25kg/m²**Exclusion criteria:**

using fat burning and weight loss drugs, multivitamin/mineral, omega-3 and green tea supplements in the past month using insulin or drugs (Metformin or Glibenclamide) for controlling blood sugar having thyroid gland disorders Pregnancy and Lactation ,athletics

AgeFrom **25 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **46**Actual sample size reached: **44****Randomization (investigator's opinion)**

Randomized

Randomization description

Individuals were randomly allocated to one of two study groups with the help of a random number table

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**National Nutrition and Food Sciences Technology
Research Institute**Street address**Faculty of Nutrition and Food Sciences, No. 7, West
Arghavan Ave., Farahzadi Blvd., Qods Town**City**

Tehran

Province

Tehran

Postal code

19395-4741

Approval date

2016-07-22, 1395/05/01

Ethics committee reference number

IR.SBMU.nnftri.Rec.1395.61

Health conditions studied**1****Description of health condition studied**

metabolic syndrome

ICD-10 code

E78, E66,

ICD-10 code descriptionmellitusHypertensive heart disease Disorders of
lipoprotein metabolism and other lipidaemias, Obesity,
Other specified diabetes**Primary outcomes****1****Description**

fasting glucose

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

enzymatic method

2**Description**

Triglycerid

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

enzymatic method

3**Description**

body weight

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

scale

4**Description**

waist circumference

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

meter

5**Description**

systolic and diastolic pressure

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

barometer

6**Description**

hs-CRP

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

ELISA

7**Description**

HDL

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

enzymatic method

8**Description**

cholesterol

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

enzymatic method

9**Description**

TNF-

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

ELISA

10**Description**

serum insulin

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

ELISA

11**Description**

intestinal microflora

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

Real-time PCR

Secondary outcomes**1****Description**

dietary intake of macronutrient

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

food recall questionnaire

2**Description**

dietary intake of energy

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

food recall questionnaire

3**Description**

LDL

Timepoint

beginning of trial/ end of trial (2 months later)

Method of measurement

Friedwald

Intervention groups**1****Description**

In the GFD group, patients were assumed to receive less than 2-gram gluten per day for eight weeks. Through the intervention process, individuals received gluten free breads. Additionally, participants were informed to not use other cereals containing glute

Category

Other

2

Description

control group, were informed to continue their regular diet for eight weeks. . A recommendation sheet containing information regarding controlling overweight and obesity was provided to participants

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition and diet therapy clinic.

Full name of responsible person

Azita Hekmatdoost

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

National Nutrition and Food Sciences Technology Research Institute

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

Faculty of Nutrition and Food Sciences

Full name of responsible person

Azita Hekmatdoost

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

In the final report

When the data will become available and for how long

5 years-2019 to 2024

To whom data/document is available

All academic researchers

Under which criteria data/document could be used

all users should cite the resours of data

From where data/document is obtainable

Azita Hekmatdoost,MD,PhD,RD Associate Prof. Dep Clin Nutrition & Dietetics, NNFTRI, SBMU, Tehran, Iran
Email:a_hekmat2000@yahoo.com

What processes are involved for a request to access data/document

by E mail

Comments