

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of rutin flavonoid supplement on glycemic status, lipid profile, plasma atherogenic index, brain derived neurotrophic factor (BDNF), some serum inflammatory biomarkers and oxidative stress in patients with type 2 diabetes mellitus

Protocol summary

Study aim

Determination of the effects of rutin flavonoid supplement on glycemic status, lipid profile, plasma atherogenic index, brain derived neurotrophic factor (BDNF), some serum inflammatory biomarkers and oxidative stress in patients with type 2 diabetes mellitus

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 patients. For randomization, block design is used.

Settings and conduct

Referred to the endocrine clinic of Golestan Hospital of Ahvaz in 2020, selection of 50 patients based on inclusion and exclusion criteria, randomization into intervention and control groups. Blinding of patients and researchers, coding by a third party who does not know the details.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, age between 20 to 60 years old in both sexes, over at least 2 years from time of diagnosis of diabetes, body mass index (BMI) less than 35, glycosylated hemoglobin (HbA1c) between 6.5 to 11% Non-inclusion criteria: Kidney failure, taking insulin, thyroid disease, anemia, pregnancy, lactation, smokers, use of compounds that interfere with the effects of the supplement, following of special diets other than the diet specific to diabetic patients, change of diet or decide to lose weight

Intervention groups

The intervention group: one rutin tablet of 1g/day (made by Solgar company, USA, containing 500 mg of pure rutin and 500 mg dicalcium phosphate, microcrystalline cellulose, plant cellulose, stearic acid, stearic magnesium, silica, glycerin) for 90 days. The control group: one placebo tablet of 1g/day (compounds similar to supplement except for rutin) for 90 days.

Main outcome variables

Fasting blood glucose, HbA1C, insulin resistance and insulin sensitivity indices, lipid profile, plasma atherogenic index and serum levels of IL-6, TAC, MDA, BDNF and Insulin

General information

Reason for update

High prevalence of Covid 19 disease and the lack of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025274N5**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **prospective**

Last update: **2021-08-21, 1400/05/30**

Update count: **2**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Ahmad Zare Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8319

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of rutin flavonoid supplement on glycemic status, lipid profile, plasma atherogenic index, brain derived neurotrophic factor (BDNF), some serum inflammatory biomarkers and oxidative stress in patients with type 2 diabetes mellitus

Public title

The effects of rutin flavonoid on type 2 diabetes mellitus

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study People between 20 to 60 years old in both sexes Over at least 2 years from time of diagnosis of type 2 diabetes mellitus Body mass index (BMI) less than 35 ($BMI \leq 35$) Glycosylated hemoglobin (HbA1c) between 6.5 to 11%

Exclusion criteria:

Reluctance of patients to participate in the study Developing complications from diabetes such as kidney failure Diabetic patients taking insulin Thyroid disease Anemia Pregnancy, lactation Traveling more than 2 weeks Smokers Use of other dietary supplements, probiotics and anti-inflammatory drugs Use of any antioxidant supplements in the last 3 months Use of immunosuppressive drugs Following of special diets other than the diet specific to diabetic patients Change of diet or decide to lose weight

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on inclusion criteria, 50 patients will randomly allocated to placebo ($n = 25$) or intervention ($n = 25$) groups. Block design based on the combined analysis and using packed envelopes is used for randomization. In fact, according to pattern and using two codes of A and B 6 groups with 4 blocks are selected. This work is repeated in 2 steps. At the end, two A and B codes are

assigned to the 2 last patients and the randomization is completed (50 patients). (step1; AABB, BBAA, ABAB, BABA, ABBA, BABA, step2; AABB, BBAA, ABAB, BABA, ABBA, BABA and AB).

Blinding (investigator's opinion)

Double blinded

Blinding description

The researchers and patients will not informed of the contents of the packets. A third person of health care does the coding. This person will not aware of the details of the research trial.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan street, Ahvaz, Khosetan, Iran

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2020-12-26, 1399/10/06

Ethics committee reference number

IR.AJUMS.REC.1399.758

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

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Fasting blood sugar

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

Secondary outcomes

1

Description

Insulin

Timepoint

Before and after the intervention

Method of measurement

ELISA

2

Description

HbA1C

Timepoint

Before and after the intervention

Method of measurement

By HPLC method and with Ds5 device

3

Description

HOMA -IR

Timepoint

Before and after the intervention

Method of measurement

$[FPG \text{ (mmol / l x FPI (FIU/ml))} / 22.5]$

4

Description

QUICKi

Timepoint

Before and after the intervention

Method of measurement

$1 / [\log (I0) + \log (G0)]$ ISQUICKi

5

Description

Plasma atherogenic index

Timepoint

Before and after the intervention

Method of measurement

log TG/HDL

6

Description

HDL-c

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

7

Description

Triglyceride

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

8

Description

LDL.C

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

9

Description

Total cholesterol

Timepoint

Before and after the intervention

Method of measurement

Using enzymatic kit method

10

Description

IL-6

Timepoint

Before and after the intervention

Method of measurement

ELISA

11

Description

TAC

Timepoint

Before and after the intervention

Method of measurement

ELISA

12

Description

MDA

Timepoint

Before and after the intervention

Method of measurement

ELISA

13

Description

BDNF

Timepoint

Before and after the intervention

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group: Every day, one tablet of 1 g rutin (containing 500 mg of pure rutin and 500 mg other compounds include di-calcium phosphate, microcrystalline cellulose, plant cellulose, stearic acid, magnesium stearic, silica, glycerin), made by the Solgar company, USA, after meals for 90 days.

Category

Treatment - Other

2

Description

Control group: One tablet of 1 g placebo/day (containing compound similar to supplement except rutin), made by the Faculty of Pharmacy of Ahvaz Jundishapur University of Medical Sciences, in terms of shape, color, size similar to supplement, after meals for 90 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology clinic of Golestan hospital

Full name of responsible person

Ahmad Zare Javid

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Ahvaz Jundishapur University of Medical Sciences,
Golestan street, Ahvaz, Khosetan,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

Street address

Vice Chancellor for Research and Technology, Ahvaz
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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Hadi Bazyar

Position

PhD Candidate of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ahmad Zare Javid

Position

Associate professor

Latest degree

Ph.D.

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

The person's information will be confidential and the results will be as collective statistics

Study Protocol

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

This clinical trial will be an research article and its results report and statistical analysis will be published to be used by therapists and researchers.

When the data will become available and for how long

If the journal has requested access to the data at any time, the data will be provided.

To whom data/document is available

Journal editors and Reviewers

Under which criteria data/document could be used

Sometimes for re-analysis or for use in meta-analysis studies

From where data/document is obtainable

Project manager

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

It should be send email to project manager and after reviewing the reason for requesting the data, they will be send

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Hadi Bazyar

Position

PhD Candidate of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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