

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effects of rutin flavonoid supplement on brain white matter neural tracts volume in type 2 diabetes mellitus patients by MRI

Protocol summary

Study aim

Determining of the effects of rutin on brain white matter neural tracts volume in type 2 diabetes patients by magnetic resonance imaging (MRI)

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 26 patients. For randomization, block design is used.

Settings and conduct

Referred to the endocrine clinic of Golestan Hospital of Ahvaz in 2020, selection of 26 people based on inclusion criteria, randomization into intervention and control groups, referral to Auxin imaging center in Ahvaz for MRI of the brain by diffusion tensor imaging (DTI) method. 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, 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% Exclusion criteria: Renal 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, history of brain surgery and brain tumors.

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

Diffusion parameters such as fractional anisotropy (FA), mean diffusivity (MD), radial diffusion (RD), axial diffusivity, white matter volume of throwing, radial and

communication fibers of the brain, and gray matter volume of brain

General information

Reason for update

High prevalence of Covid 19 disease and the lack of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025274N6**

Registration date: **2021-01-10, 1399/10/21**

Registration timing: **prospective**

Last update: **2021-08-20, 1400/05/29**

Update count: **2**

Registration date

2021-01-10, 1399/10/21

Registrant information

Name

Ahmad Zare Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8319

Email address

zarejavid-a@ajums.ac.ir

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 brain white matter neural tracts volume in type 2 diabetes mellitus patients by MRI

Public title

The effects of rutin supplement on the brain of type 2 diabetes mellitus patients

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:

Developing complications from diabetes such as renal failure Diabetic patients taking insulin Thyroid disease Anemia Pregnancy, lactation 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, History of brain surgery and brain tumors.

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients in each of the study groups (supplement or placebo) will be done by "Random allocation software" using classified randomized blocking method (block size: 4). In addition, in order to reduce selection bias error, allocation concealment will be used. This will be done by assigning unit codes (two codes A and B) to each patient's tablets. In this way, 26 patients will be randomly allocated to placebo ($n = 13$) or intervention ($n = 13$) groups. In fact, each patient will receive a can containing code A or B, and eventually 13 patients will receive cans containing code A and 13 patients will receive cans containing code B.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, the doctor, researcher, and patients will be blinded to the study groups. Before starting the study, the cans containing the respective tablets will be coded by a person other than the researcher (this person will not aware of the details of the research) to A and B, so that the type of received tablets in each group will be blinded for researcher. Also, placebo and supplement tablets will be similar in terms of color, shape, size and taste. In addition, cans containing the supplement and placebo will be quite similar.

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.1399.777

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**

Fractional anisotropy (FA)

Timepoint

Before and after the intervention

Method of measurement

Using Diffusion Tensor Imaging (DTI) and analysis with functional magnetic resonance imaging of the brain software library (FSL) software

2

Description

MD: Mean diffusivity

Timepoint

Before and after the intervention

Method of measurement

Using Diffusion Tensor Imaging (DTI) and analysis with functional magnetic resonance imaging of the brain software library (FSL) software

3

Description

RD: Radial diffusivity

Timepoint

Before and after the intervention

Method of measurement

Using Diffusion Tensor Imaging (DTI) and analysis with functional magnetic resonance imaging of the brain software library (FSL) software

4

Description

AD: Axial diffusivity

Timepoint

Before and after the intervention

Method of measurement

Using Diffusion Tensor Imaging (DTI) and analysis with functional magnetic resonance imaging of the brain software library (FSL) software

5

Description

The volume of white matter of the throwing, radial and communication fibers of the brain

Timepoint

Before and after the intervention

Method of measurement

Using Diffusion Tensor Imaging (DTI) and analysis with functional magnetic resonance imaging of the brain software library (FSL) software

6

Description

The volume of gray matter of the brain

Timepoint

Before and after the intervention

Method of measurement

Using Diffusion Tensor Imaging (DTI) and analysis with functional magnetic resonance imaging of the brain software library (FSL) software

Secondary outcomes

empty

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

Street address

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

City

Ahvaz

Province

Khouzestan

Postal code

7853167465

Phone

+98 74 3333 1257

Email

ahmaddjavid@gmail.com

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

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Phone

+98 61 3336 2414

Email

itc@ajums.ac.ir

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

Street address

Department of Nutrition, School of Allied Medical
Sciences, Ahvaz Jundishapur University of Medical
Sciences, Golestan St., Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

7853167465

Phone

+98 61 3333 0747

Email

hadibazyar2015@gmail.com

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Ahmad Zare Javid

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, School of Allied Medical
Sciences, Jundishapur University of Medical Sciences,
Golestan St., Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6163764754

Phone

+98 74 3333 1257

Email

ahmaddjavid@gmail.com

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

Street address

Department of Nutrition, School of Allied Medical
Sciences, Jundishapur University of Medical Sciences,
Golestan St., Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

7853167465

Phone

+98 61 3333 0747

Email

hadibazyar2015@gmail.com

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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

This clinical trial will be an research article and its

protocol, 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

Mail to ahmaddjavid@gmail.com

Comments