Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 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 ≤ 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
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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
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 updating data

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PhD Candidate of Nutrition

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Other areas of specialty/work
Nutrition

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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

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