Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effects of rutin flavonoid supplement consumption on blood pressure, heart rate, quality of life and some serum antioxidant enzymes in type 2 diabetic patients

Protocol summary

Study aim
The effects of rutin flavonoid on type 2 diabetes mellitus

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 48 patients. For randomization, block design is used.

Settings and conduct
Referred to the endocrine clinic of Golestan Hospital of Ahvaz in 2021, selection of 48 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: 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: 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,

Intervention groups
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), after meals for 90 days. Control group: One tablet of 1 g placebo/day (containing compound similar to supplement except rutin), after meals for 90 days.

Main outcome variables
Systolic and diastolic blood pressure, pulse pressure, mean arterial pressure, heart rate, quality of life, serum levels of catalase, superoxide dismutase and glutathione peroxidase

General information

Reason for update
High prevalence of Covid 19 disease and the lack of sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20170116031993N5**
Registration date: **2021-05-22, 1400/03/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-07, 1400/08/16**
Update count: **1**

Registration date
2021-05-22, 1400/03/01

Registrant information

Name
Hadi Bazyar

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

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 consumption on blood pressure, heart rate, quality of life and some serum antioxidant enzymes in type 2 diabetic patients

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 ≤ 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,
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **48**
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, 48 patients will be randomly allocated to placebo (n = 24) or intervention (n = 24) groups. In fact, each patient will receive a can containing code A or B, and eventually 24 patients will receive cans containing code A and 24 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
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Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2021-05-15, 1400/02/25
Ethics committee reference number
IR.AJUMS.REC.1400.110

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
Systolic blood pressure, diastole, pulse pressure, mean arterial pressure and heart rate
Timepoint
Before and after the intervention
Method of measurement
Using digital sphygmomanometer

2

Description
Quality of Life
Timepoint
Before and after the intervention
Method of measurement
Questionnaire 36 items

3

Description
Catalase enzyme
Timepoint
Before and after the intervention
Method of measurement
ELISA kit

4

Description
Superoxide dismutase enzyme
Timepoint
Before and after the intervention
Method of measurement
ELISA kit

5

Description
Glutathione peroxidase
Timepoint
Before and after the intervention
Method of measurement
ELISA kit

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
Hadi bazyar
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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
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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

Mail to hadibazyar2015@gmail.com

Comments