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Effect of resveratrol on cognitive functions and inflammation in a population of older adults with type 2 diabetes mellitus

Submission date
24/07/2021

Recruitment status
No longer recruiting

Registration date
27/09/2021

Overall study status
Completed

Last Edited
09/10/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Currently, people live longer and this has caused an increase in the presence of diseases such as high blood pressure, obesity and type 2 diabetes mellitus (DM2), among others.
Oxidative stress (an imbalance between free radicals and antioxidants in your body) is thought to play a role in complications of diabetes.
Resveratrol (RV) is part of a group of compounds called polyphenols. They're thought to act like antioxidants, protecting the body against damage that can put you at higher risk for things like cancer and heart disease. It's in the skin of red grapes, but you can also find it in peanuts and berries.
The main objective of this project is to know how resveratrol works on markers of oxidative stress, chronic inflammation and cognitive functions in a group of elderly patients with DM2.

Who can participate?
Adults over 60 years of age, residents of Mexico City, diagnosed with DM2, without intake of alcohol, tobacco, or antioxidant supplements or hormone replacement in the case of women.

What does the study involve?
Participants are randomly divided into three groups: i) Experimental A (500 mg of RV), ii) Experimental B (1000 mg of RV) and iii) Placebo. Oxidative stress markers, chronic inflammatory response and cognitive functions will be measured in each subject pre and post-intervention at 6 and 12 months.

What are the possible benefits and risks of participating?
The tests carried out and the RV will have no cost. The information collected will be strictly confidential. The results of glucose, lipid profile, kidney profile, hematic biometry and glycated hemoglobin will be delivered to the patients for the control and monitoring of their health status.
There is no health risk, RV has been shown to be safe and approved for use in humans. The taking of blood samples will be carried out by qualified personnel, with new and disposable material.

Where is this study run from?
National Autonomous University of Mexico (Mexico)

When is the study starting and how long is it expected to run for?
May 2020 to October 2022

Who is funding this study?
National Autonomous University of Mexico

Who is the main contact?
Dr Mirna Ruiz-Ramos, mirna1411@yahoo.com.mx

Study website
http://www.zaragoza.unam.mx/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IN308120

Study information

Scientific Title
Effect of oral administration of resveratrol on markers of oxidative stress, inflammation and cognitive functions in a population of older adults with type 2 diabetes mellitus

Study objectives
Taking into account the scientific reports regarding the effectiveness of resveratrol intake on glycemic control and its antioxidant, anti-inflammatory and neuroprotective properties, it is assumed that the oral administration of resveratrol will improve the levels of oxidative stress markers and chronic inflammation, as well as performance in cognitive tests, in addition to stabilizing biochemical markers in patients with type 2 diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2021, Ethics, Bioethics and Biosafety Committee of the Research Committee of Facultad de Estudios Superiores Zaragoza, UNAM (C. Bonilla 66, Ejercito de Oriente, Delegación Iztapalapa, 09230, Mexico; +521 5556230724; div.posgrado.investigacion@zaragoza.unam.mx), ref: FESZ-CE/20-118-01

Study design
Single-centre interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
https://www.zaragoza.unam.mx/proceso-inflamatorio-cronico-y-enfermedades-cronicas/

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
The sample will be randomly divided into three groups:
1. Experimental A will receive a capsule with 500 mg of resveratrol (RV) daily for 12 months
2. Experimental B will receive two capsules with 500 mg RV daily for 12 months
3. Placebo will receive a capsule of identical appearance to those of the other groups daily for 12 months

All participants must be under similar antidiabetic treatment regimens (metformin and/or glibenclamide) at the time of their inclusion in the study.
All patients will be verbally informed and signed a consent form.
In order to evaluate the effect of oral administration of resveratrol on cognitive functions, the following will be carried out: Rey's auditory-verbal learning test, series of digits and symbols test and the trace test.
To evaluate the effect on oxidative stress markers, isoprostanes, DNA damage, total antioxidant activity and antioxidant capacity of the enzymes superoxide dismutase and glutathione peroxidase will be measured.
To evaluate the effect on chronic inflammation markers, the following will be measured: CRP, IL1, IL6, TNF-a and IL10
Finally, to evaluate the degree of diabetic control, the following will be carried out: measurement of glucose levels, HBA1c, lipid profile (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides), kidney profile (uric acid, creatinine, urea) and blood pressure.

Intervention Type
Supplement

Primary outcome measure
Cognitive functions that are measured at the beginning and at 12 months by:
1. Rey's auditory-verbal learning test
2. The digit and symbol string test
3. The stroke test

Secondary outcome measures
1. Markers of oxidative stress measured at the beginning of the study and at 12 months using:
1.1 Isoprostanes, by enzyme-linked immunosorbent assay (ELISA)
1.2 DNA damage by alkaline electrophoresis
1.3 Total antioxidant activity, by spectrophotometric technique using a commercial kit from Randox Laboratories Ltd.
1.4 The antioxidant capacity of the enzymes superoxide dismutase and glutathione peroxidase, by spectrophotometric technique using a
commercial kit from Randox Laboratories Ltd.
2. Markers of chronic inflammation at baseline and at 12 months measured using:
2.1 C-reactive protein (CRP), by nephelometry using a commercial kit from Randox Laboratories Ltd.
2.2 IL1, IL6, TNF-α and IL10, will be performed by flow cytometry with a commercial BD kit.
3. Degree of control measured at the beginning and at 12 months through levels of:

3.1 glucose, HBA1c, lipid profile (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides), kidney profile (uric acid, creatinine, urea) that
will be carried out in an automated equipment (Selectra Junior), and commercial kits will be used (Randox Laboratories Ltd.).
3.2 Blood pressure, measured by trained nursing personnel.

Overall study start date
10/05/2020

Completion date
10/10/2022

Eligibility

Key inclusion criteria
1. Clinical diagnosis of diabetes mellitus type 2
2. People over 60 years of age
3. Residence in Mexico City
4. Either sex

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Smoking or alcoholism
2. People who have taken antioxidant supplements or anti-inflammatories in the last 6 months
3. Without replacement hormones, in the case of women

Date of first enrolment
16/05/2020

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Guatemala

Mexico

Study participating centre
Gerontology Research Unit, FES Zaragoza (Unidad de Investigación en Gerontología, FES Zaragoza, UNAM)
Batalla 5 de mayo s/n
Esquina Fuerte de Loreto
Ejercito de Oriente
Delegación Iztapalapa
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.unam.mx/index/en

ROR
https://ror.org/01tmp8f25

Funder(s)

Funder type
University/education

Funder Name
Universidad Nacional Autónoma de México

Alternative Name(s)
National Autonomous University of Mexico, UNAM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Mexico

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
14/11/2022

Individual participant data (IPD) sharing plan
The data generated during the study will be available upon request to the researcher, PhD. Mirna Ruiz Ramos, by requesting it by mail to the email address mirnar@comunidad.unam.mx, which will be available from September 2023.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/04/2023	09/10/2024	Yes	No