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Study on the benefit of quercetin intake in diabetic patients treated with antidiabetic tablets.

Submission date
20/11/2022

Recruitment status
No longer recruiting

Registration date
17/01/2023

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Quercetin has a scientifically proven anti-oxidant, anti-inflammatory and anti-coagulant effect. Nevertheless, the anti-aging effect of quercetin has been studied exclusively in vitro (test-tube experiments) with promising results. Thus, research is needed to examine quercetin's anti-aging effect in humans. The aim of this study is to investigate the benefit of quercetin in improving health and daily life.

Who can participate?
The selection of participants will be performed in a random manner from the registered population of responsibility of the 4th Public Health Unit (TOMY) of Heraklion and will include 100 patients with type II diabetes, treated with antidiabetic tablets, over 50 years old, who will be asked to participate in this research.

What does the study involve?
Participants will be randomly allocated to receive the quercetin supplement (intervention group) or not (control group).
Laboratory tests will be performed at the beginning and end of the study in both groups. The research is divided into the following parts: A pool of potential patients-participants will be established by recording and assessing demographic, anthropometric characteristics and living habits (gender, age, smoking habits, diet, physical activity, medical treatment). Of these, those who after thorough information accept and consent to participate will be included, while particularly vulnerable individuals will be excluded.
The total participation time is 8 months. The study will be conducted in the 4th TOMY (Local Health Unit) of Heraklion, 7th HPE (Health District) of Crete.
The time and dosage of taking quercetin will be based on the indications of supplement in question. Specifically, the intervention group will be given 500 mg of quercetin per day for 12 weeks, then stopped for 8 weeks and re-administered for another 12 weeks.
Blood samples will be taken from participants for laboratory testing at baseline (t=0) and end of the study (t= 8 mo). The sample is necessary to measure telomere length (genetic data), which will give us information about cellular aging.

At the same time, the participants will be asked to consent to the measurement of their anthropometric indicators, such as BMI and waist circumference, while they will also undergo spirometry with a pikometer in the aforementioned phases.

What are the possible benefits and risks of participating?
The risks associated with quercetin supplementation are considered minimal. However, one potential inconvenience may be the time required to complete the study.
Although there are no direct benefits resulting from the participation in this research, it may help by highighting the action of quecetin and subsequently facilitating the adoption of targeted interventions. Participants may benefit from the action of this supplement. There will be no personal compensation for participation in the study.

Where is the study run from?
This study will be conducted in the 4th Local Health Unit of Heraklion (TOMY), Crete.

When is the study starting and how long is it expected to run for?
January 2021 to January 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
PhD Candidate Aikaterini Mantadaki
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2934/253

Study information

Scientific Title
Study on the benefit of quercetin intake in diabetic patients treated with antidiabetic tablets. A two-arm, prospective randomized control clinical trial (interventional vs observation group) in primary health care.

Study objectives
In the present study, the hypothesis that the intake of quercetin could be related to an improvement of the body's antioxidant status and an antiaging effect will be examined.
The main research question investigates the occurrence of antiaging action. The secondary question concerns the antioxidant effect resulting from the intake of quercetin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/08/2021, University of Crete Research Ethics Committee (Rectors Office, University of Crete, Voutes University Campus Heraklion, Crete, 71300, Greece; +302810395206; ehde@uoc.gr), ref: 104/20.08.2021.

Study design
Interventional randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions
This is an interventional study, in which a nutritional supplement will be used in a group of diabetic patients treated with antidiabetic tablets, who will receive the supplement in question alongside their treatment (intervention group) and a group which will not be administered to the nutritional supplement alongside the treatment (control group). The nutritional supplement that will be administered is quercetin. The time and dosage of supplementation of quercetin will respect the indications of the nutritional supplement. Specifically, the intervention group will be given 500 mg of quercetin per day for 12 weeks, which will then be ceased for 8 weeks and re-administered for another 12 weeks. A random allocation ratio will be used for the recruitment of the patients in the intervention and control group, taking into account age and gender.

Intervention Type
Supplement

Primary outcome measure
Telomere length will be measured using quantitative Polymerase Chain Reaction (qPCR), before (t=0) and after the intervention (t=32 weeks) for both groups

Secondary outcome measures
1. [CBC] measured using [Beckman Coulter method of counting and sizing], before and after the intervention for both study groups
2. [IL-6] measured using [electrochemiluminescence] before and after the intervention for both study groups
3. [reticulocytes] measured using [Methylene blue stain (NMB)] before and after the intervention for both study groups
4. [hemoglobin] measured using [Beckman Coulter method of counting and sizing] before and after the intervention for both study groups
5. [WBC] measured using [Beckman Coulter method of counting and sizing] before and after the intervention for both study groups
6. [CRP] measured using [latex indirect agglutination (LIA)] before and after the intervention for both study groups
7. [HbA1c] measured using [high-performance liquid chromatography (HPLC)] before and after the intervention for both study groups
8. [TC] measured using [enzymatic method] before and after the intervention for both study groups
9. [LDL] measured using [Friedewald calculation] before and after the intervention for both study groups
10. [TGL] measured using [GPO/POD] before and after the intervention for both study groups
11. [creatinine] measured using [Creatinine amidohydrolase enzymatic method] before and after the intervention for both study groups
12. [serum nitrogen] measured using [Nesslerization] before and after the intervention for both study groups
13. [DHEAS] measured using [DHEA Sulfate Test] before and after the intervention for both study groups,
14. [25-OH-vitamin D] measured using [immunoassay, Liaison 25(OH) Vitamin D Total assay] before and after the intervention for both study groups
15. [FEV1] measured using piko-spirometry before and after the intervention for both study groups

Overall study start date
29/01/2021

Completion date
29/01/2024

Eligibility

Key inclusion criteria
Eligible participants will be type II diabetes patients treated with antidiabetic tablets, with an age over 50 years who belong to the registered population of responsibility of the 4th Local Health Unit (TOMY) of Heraklion.

Participant type(s)
Patient

Age group
Other

Lower age limit
50 Years

Sex
Both

Target number of participants
100 (50 patients in the control group, 50 patients in the interventional arm)

Total final enrolment
100

Key exclusion criteria
Highly vulnerable individuals will be excluded, following the relevant legal and ethical rules. The above cases are also excluded:
1. Gestational diabetes (breastfeeding/pregnancy),
2. Maturity-onset diabetes of the young (MODY),
3. Pancreatogenic diabetes (T3CDM),
4. Heart, liver or kidney disease,
5. Serious psychiatric illness or addiction,
6. Patients with comorbidities such as cancer, AIDS, neoplastic diseases,
7. Organ transplant patients, patients under immunosuppressive therapy,
8. Patients who have recently suffered a cardiovascular event, within three months before the start of the study,
9. Patients using other antioxidant supplementations,
10. Patients with a requirement for long-term use of aspirin, other than low dosage for protection against cardiovascular events, or NSAIDs,
11. Patients participating in another interventional clinical study,
12. Patients with planned surgery or other interventional procedure requiring systemic anesthesia during the study.

Date of first enrolment
07/02/2023

Date of final enrolment
30/05/2023

Locations

Countries of recruitment
Greece

Study participating centre
4th Local Health Unit of Heraklion (TOMY)
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71303

Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/00dr28g20

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
18/11/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitivity of the genetic, bioclinical and personal data of study participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/08/2024	05/02/2025	Yes	No
Results article		15/06/2024	05/02/2025	Yes	No
Results article		14/04/2024	05/02/2025	Yes	No