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The effect of vitamin D on people with prediabetes

Submission date	Recruitment status
27/01/2022	No longer recruiting
Registration date	**Overall study status**
28/01/2022	Completed
Last Edited	**Condition category**
14/02/2024	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Prediabetes is a serious health condition where blood sugar levels are higher than normal, but not high enough yet to be diagnosed as type 2 diabetes. Data are scarce on the effectiveness of vitamin D at improving the blood sugar levels of elderly people with prediabetes. The aim of this study is to investigate the effect of vitamin D supplementation on blood sugar markers of Greek people with prediabetes aged 60 years or above, over a 12-month period.

Who can participate?
Men and women with prediabetes aged 60 years and older living in Thessaloniki, Greece

What does the study involve?
Participants are randomly allocated to a weekly vitamin D3 dose of 25,000 IU or nothing on top of lifestyle measures. Body measurements and blood sugar markers are assessed at the start of the study and after 3, 6 and 12 months.

What are the possible benefits and risks of participating?
The possible benefits include an improvement in vitamin D status, which is known to be important for skeletal health, particularly among the elderly, and an improvement in blood sugar markers in supplemented individuals. There are no expected risks.

Where is the study run from?
Aristotle University (Greece)

When is the study starting and how long is it expected to run for?
February 2016 to February 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Assoc. Professor Kalliopi Kotsa
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1278/6-10-15

Study information

Scientific Title
The effect of vitamin D supplementation on glycemic status of elderly people with prediabetes: a 12-month open-label, randomized-controlled study

Study objectives
It is hypothesized that vitamin D supplementation has optimal effects on glycemic markers of elderly people with prediabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 19/04/2016, the Ethics Committee of the Aristotle University of Thessaloniki (Faculty of Medicine, Aristotle University of Thessaloniki, University Campus, Building of the new Amphitheatres, PC 54124, Thessaloniki, Greece; +30 (0)2310999338, bioethics@med.auth.gr, sakkageor@auth.gr), ref: 260/19-04-16

Study design
Interventional 12-month open-label single-centre randomized-controlled study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of the development of diabetes in people with prediabetes

Interventions
Among the 381 individuals initially screened, 105 were diagnosed with prediabetes and 90 eventually met the inclusion criteria and agreed to participate. They were randomly assigned by computer code to receive a weekly dose of vitamin D3 of 25,000 IU in the form of oral solution (intervention group; n = 45) or nothing (control group; n = 45). Both groups were advised to adopt specific lifestyle changes according to the ADA recommendations for the prevention of diabetes, namely at least 150 min per week of moderate-intensity aerobic activity, and target a 7% weight loss within 3 months by adhering to the Mediterranean diet. Participants were seen monthly for the first 3 months of the follow-up period and subsequently every 3 months until the end of the study. Each visit included a consultation with both a physician and a dietitian to resolve potential issues, while subjects were contacted by telephone monthly by members of the research team to ensure adherence to the diet and compliance with supplement use. The latter was also determined from the number of empty medication boxes returned at each visit. Anthropometric and glycemic markers were assessed at baseline, 3, 6, and 12 months.

Intervention Type
Supplement

Primary outcome(s)
1. Fasting glucose measured using the Cobas INTEGRA clinical chemistry system at 3, 6, and 12 months after the start of vitamin D supplementation
2. Glycated hemoglobin values measured using the ADAMS HA-8160 high-performance liquid chromatography method at 3, 6, and 12 months after the start of vitamin D supplementation

Key secondary outcome(s))
1. Percentage of total participants who progressed to diabetes or returned to normoglycemia based on fasting glucose and 2 h glucose in 75 g oral glucose tolerance test (OGTT) values at 12 months after the start of vitamin D supplementation
2. Anxiety measured with the State-Trait Anxiety Inventory tool at 6 and 12 months after the start of vitamin D supplementation
3. Depression measured with the Patient Health Questionnaire-9 tool at 6 and 12 months after the start of vitamin D supplementation

Completion date
01/02/2020

Eligibility

Key inclusion criteria
1. Men and women with prediabetes aged 60 years and older
2. Listed on the registry of the Open Care Center for the Elderly of the Municipality of Eastern Thessaloniki, Greece.
3. Prediabetes diagnosed according to the criteria of the American Diabetes Association (ADA), either by impaired fasting plasma glucose (IFG) [fasting plasma glucose (FPG): 100–125 mg/dl] or impaired glucose tolerance (IGT) [2-h plasma glucose in 75 g oral glucose tolerance (OGTT): 140–199 mg/dl] or by values of glycated hemoglobin (HbA1c) between 5.7% (39 mmol/mol) and 6.4% (46 mmol/mol)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 years

Sex
All

Total final enrolment
90

Key exclusion criteria
1. Pre-existing diabetes mellitus
2. Normal glucose levels
3. Any medical conditions that could potentially affect the outcomes of the study or increase the risk of complications following vitamin D supplementation (nephrolithiasis, hypercalcemia, hyperparathyroidism, sarcoidosis, and chronic renal disease [stages 3 to 5 / estimated glomerular filtration rate <45 ml/min/1.73m^2])
4. Malignancies
5. Inflammatory or rheumatic diseases
6. Psychiatric conditions

Date of first enrolment
01/10/2017

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Greece

Study participating centre
AHEPA University Hospital
Division of Endocrinology and Metabolism
First Department of Internal Medicine
Medical School
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Sponsor information

Organisation
Aristotle University of Thessaloniki

ROR
https://ror.org/02j61yw88

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Access to trial IPD can be requested by qualified researchers engaging in independent scientific research, and will be provided following review and approval of a research proposal and Statistical Analysis Plan (SAP) and execution of a Data Sharing Agreement (DSA).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/02/2022	16/02/2022	Yes	No
Results article		20/09/2022	14/02/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes