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Effect of olive oil enriched in oleanolic acid on the incidence of type 2 diabetes mellitus in patients with pre-diabetes

Submission date	Recruitment status
25/04/2009	No longer recruiting
Registration date	**Overall study status**
03/11/2009	Completed
Last Edited	**Condition category**
01/08/2019	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0037/2008

Study information

Scientific Title
Effect of olive oil enriched in oleanolic acid on the incidence of type 2 diabetes mellitus in patients with pre-diabetes: a multicentre randomised double-blind controlled trial

Acronym
PREDIABOLE

Study objectives
A dietary intervention based on the consumption of olive oil rich in oleanolic acid, reaching a concentration of 600 mg/kg, reduces the incidence of type 2 diabetes mellitus by at least 20% in patients with pre-diabetes (impaired glucose tolerance and impaired fasting glucose) compared to another group that consumed the same amount of commercial olive oil not reinforced with the aforementioned acid.

Please note that as of 09/11/09 this record has been updated. All updates can be found in the relevant field with the above update date. Please also note that the start and end dates of this trial have been changed from 20/05/2009 and 31/12/2009 to 01/10/2009 and 31/12/2012, respectively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and Ethics Committee of the Sevilla Primary Care Division gave approval on the 20th of March 2008.

Study design
Multicentre randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Dr Jose Manuel Lozano-Santos [josemanuel.santos@juntadeandalucia.es] or Dr Jose Lapetra Peralta [jose.lapetra.sspa@juntadeandalucia.es] to request a patient information sheet

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

Interventions
At each visit, patients will receive the oil for their consumption over 3 months. In both of the groups every 3 months, a visit will be made to provide a customised dietetic intervention. The amount of oil to consume is 55.5 ml/day, taken raw. In the case of the oil enriched with oleanolic acid, this would contribute 40 mg/day to the participants diet.

Added 9/11/09:
1. Baseline variables (BV) and patient data (PD) measured at visit 0 (baseline visit):
1.1. History of type 2 diabetes mellitus in first-degree relative.
1.2. Time developments of prediabetes.
1.3. History of hypertension, ischemic heart disease, cerebrovascular disease and peripheral arterial disease.
1.4. Smoking status and alcohol consumption
1.5. Physical Exercise.
2. Lifestyle information also assessed at baseline

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Oleanolic acid

Primary outcome measure
Incidence of diabetes, diagnosed according to basal blood glucose or oral glucose overload, conducted every 6 months or 12 months respectively after entry into the study, according to recent criteria of the American Diabetes Association (ADA) (a fasting plasma glucose ≥ 126 mg /dl or symptoms of hyperglycaemia and casual plasma glucose ≥ 200 mg/dl or a plasma glucose value at 2 hours after an oral overload of 75 g of glucose ≥ 200 mg/dl. In the absence of unequivocal hyperglycaemia, these criteria should be confirmed by repeating the test on a different day.)

Secondary outcome measures
1. Body mass index (BMI = weight in kilograms divided by the square of height in metres) measured at baseline
2. Waist circumference (abdominal perimeter in cm)
3. Systolic blood pressure (SBP) and diastolic blood pressure (DBP)
4. Pulse pressure (SBP - DBP)
5. Lipid profile:
5.1. Total cholesterol (mg/dl)
5.2. Triglycerides (mg/dl)
5.3. High density lipoprotein (HDL) cholesterol (mg/dl)
5.4. Low density lipoprotein (LDL) cholesterol (mg/dl)
6. Fasting plasma glucose (mg/dl)
7. Insulin (IU/ml)
8. HOMA index (Homeostasis Model Assessment): uU/ml x mmol/L/22.5 (HOMA =[glucose (millimoles per litre) x insulin (microunits per millilitre)]/22.5) was used as a measure of insulin resistance (IR)
9. Haemoglobin A1c (HbA1c) (%)

10. Plasma glucose at 2 hours after oral glucose overload (75 g) measured at months 12 and 24 (and at baseline where applicable)

Added 09/11/09:
11. Personal interview (PI) carried out at baseline and months 3, 6, 9, 12, 15, 18, 21 and 24 to assess:
11.1. hypocaloric diet
11.2. physical exercise habits
11.3. toxic habits
12. Assessment of Compliance (AC) at months 3, 6, 9, 12, 15, 18, 21 and 24

Physical Examination (PE) (pts. 2-4 above) measured at baseline, months 3, 6, 9, 12, 15, 18, 21, and 24.
Laboratory variables monitored (LVM) (pts. 5-9 above) measured at baseline, months 6, 12, 18 and 24.

Overall study start date
20/05/2009

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Current information as of 09/11/09:
1. Men or women with an age range between 30 and 80 years
2. Body mass index ≥ 25 kg/m^2 and < 40 kg/m^2
3. Acceptance to participate in the study and signed the corresponding informed consent

Initial information at time of registration:
1. Men or women with an age range between 30 and 80 years
2. Body mass index ≥ 25 kg/m^2
3. Acceptance to participate in the study and signed the corresponding informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
216 patients

Total final enrolment
176

Key exclusion criteria

Current information as of 09/11/09:
1. Diabetes at the time of admission to the study:
1.1. Glycaemia baseline ≥ 126 mg/dl or glycaemia 2 hours after the oral overload
1.2. 75 g of glucose ≥ 200 mg/dl
1.3. Diabetes confirmed by a physician and confirmed by other clinical data
1.4. In antidiabetic treatment (oral and/or insulin)
2. Alcohol dependence syndrome or any other addiction
3. Physical, mental or intellectual limitation to take part in a study of dietary intervention
4. Difficulty or lack of predisposition to change food habits
5. Drugs or medical conditions that interfere with the diagnosis of diabetes:
5.1. Beta-blockers
5.2. Systemic glucocorticoids
5.3. Selective inhibitors of the reuptake of serotonin at doses indicated for weight reduction
5.4. Other drugs for weight reduction (orlistat and sibutramine)
5.5. Thyroid Disease suboptimal treatment
5.6. Other endocrine diseases (such as Cushing's disease, acromegaly)
5.7. Fasting triglycerides > 600 mg/dl despite treatment
6. Conditions or circumstances which may affect the conduct of the trial:
6.1. Inability to communicate with the researchers conducting the intervention
6.2. Not willing to accept the treatment assigned by randomisation
6.3. Participation in another project that could interfere with this project
6.4. Loss of weight for any reason superior to 10 % in the last three months, except postpartum
6.5. Inability to walk 400 meters in 10 minutes without stopping
7. Cancer in the last 5 years that needed treatment, unless the prognosis is good
8. Systolic blood pressure ≥ 180 mmHg and/or diastolic blood pressure ≥ 110 mmHg
9. Pregnant women of childbearing age, if:
9.1. Currently pregnant or within 3 months postpartum
9.2. Lactating
9.3. Pregnancy planned during the study period

Initial information at time of registration
1. Diabetes at the time of admission to the study:
1.1. Glycaemia baseline ≥ 126 mg/dl or glycaemia 2 hours after the oral overload
1.2. 75 g of glucose ≥ 200 mg/dl
1.3. Diabetes confirmed by a physician and confirmed by other clinical data
1.4. In antidiabetic treatment (oral and/or insulin)
2. Alcohol dependence syndrome or any other addiction
3. Physical, mental or intellectual limitation to take part in a study of dietary intervention
4. Difficulty or lack of predisposition to change food habits
5. Drugs or medical conditions that interfere with the diagnosis of diabetes:
5.1. Thiazide diuretics
5.2. Beta-blockers
5.3. Systemic glucocorticoids
5.4. Selective inhibitors of the reuptake of serotonin at doses indicated for weight reduction
5.5. Other drugs for weight reduction (orlistat and sibutramine)
5.6. Thyroid Disease suboptimal treatment
5.7. Other endocrine diseases (such as Cushing's disease, acromegaly)
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Date of first enrolment
20/05/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Spain

Study participating centre
San Pablo Health Center (Primary Care Division of Sevilla).
Sevilla
Spain
41005

Sponsor information

Organisation
Andalusian Regional Ministry of Health (Consejería de Salud de la Junta de Andalucía) (Spain)

Sponsor details
Avda de la Innovación s/n
Sevilla
Spain
41020

Sponsor type
Government

Website
http://www.juntadeandalucia.es/salud

ROR

https://ror.org/03q4c3e69

Funder(s)

Funder type
Government

Funder Name
Andalusian Regional Ministry of Health (Consejería de Salud de la Junta de Andalucía) (Spain) (ref: 0037/2008)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2019	01/08/2019	Yes	No