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Evaluation of the effect of supplementation with omega-3 fatty acids and vitamin D on blood sugar, lipids, cholesterol and inflammation markers, and body weight, in patients with diabetes mellitus

Submission date
19/10/2016

Recruitment status
No longer recruiting

Registration date
24/10/2016

Overall study status
Completed

Last Edited
10/07/2018

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
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). One of the most important ways of treating T2DM is through lifestyle changes, such as eating more healthily and exercising more. Nutritional supplements may be a good way of improving health in people with diabetes. The aim of this study is to find out whether supplements containing vitamin D, omega 3 or both can help patients better control their blood sugar levels.

Who can participate?
Patients aged between 25 and 55 who are type 2 diabetes.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take three gelcaps (gel capsules) containing omega 3 supplements to take daily at meal times for 24 weeks. Those in the second group receive three gelcaps containing vitamin D supplements to take daily at meal times for 24 weeks. Those in the third group take three gelcaps containing vitamin D and three containing omega 3, daily at mealtimes for 24 weeks. Those in the fourth group take gelcaps containing cornstarch, which acts as a placebo (dummy pill) daily at mealtimes for 24 weeks. At the start of the study and then after 24 weeks, participants in all groups have their height, weight and diet assessed as well as providing a blood sample to test for blood sugar and fat levels.

What are the possible benefits and risks of participating?
Participants benefit from receiving information about their health free of charge, as well as

possibly benefiting from the supplements they are taking. All supplements used in the study are available commercially and are safe to use so there are no known risks involved with participating. There is a small risk of pain or bruising from blood tests.

Where is the study run from?
The study is run by Universidad Autónoma del Estado de México and takes place in nine health centres (Mexico)

When is the study starting and how long is it expected to run for?
September 2015 to April 2018

Who is funding the study?
Consejo Nacional de Ciencia y Tecnología (Mexico)

Who is the main contact?
Dr Roxana Valdes-Ramos
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UAEM 212946

Study information

Scientific Title

Effect of omega-3 fatty acid supplementation and vitamin D on the immuno-inflammatory process in patients with type 2 diabetes mellitus in Mexico

Study objectives
1. A higher concentration of plasma polyunsaturated fatty acid and vitamin D will result in a better antiinflammatory profile in patients with type 2 diabetes mellitus
2. Type 2 diabetes mellitus patients supplemented with polyunsaturated fatty acids and vitamin D will have a better antiinflammatory profile in comparison with patients supplemented with polyunsaturated fatty acids of vitamin D

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics and Research Committes of the Faculty of Medicine of the Universidad Autónoma del Estado de México, 31/01/2013

Study design
Placebo-controlled cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Type 2 Diabetes Mellitus

Interventions
Participating health clinics are randomised to one of four groups.

Group 1: Participants receive three gelcaps (Vitamin D-3 General Nutrition Centers™) daily, to be consumed one per meal time, with a total of 3300mg of fatty acids as follows: EPA 765 mg and DHA 240 mg per capsule.

Group 2: Participants receive three gelcaps (Fish Oil 1000 General Nutrition Centers™) daily, to be consumed one per meal time, with a total of 3000 IU of vitamin D3, each containing Cholecalciferol (equivalent to 1000 IU of Vitamin D3) 0.250mg.

Group 3: Participants receive three gelcaps (Vitamin D-3 General Nutrition Centers™) daily, to be consumed one per meal time, with a total of 3300mg of fatty acids as follows: EPA 765 mg and DHA 240 mg per capsule, and three gelcaps (Fish Oil 1000 General Nutrition Centers™) daily, to

be consumed one per meal time, with a total of 3000 IU of vitamin D3, each containing Cholecalciferol (equivalent to 1000 IU of Vitamin D3) 0.250mg. That is one capsule of each supplement per meal time for a total of six per day.

Group 4: Participants receive three capsules filled with cornstarch per day, to be consumed one per meal time.

Once the patients were assigned to the supplement groups, they were called to attend their clinic for the baseline evaluation and given their four-week supplements and their subsequent appointment. At every four-week appointment, patients underwent a 24-food recall, the two adherence tests and received their next four-week supplement flasks. The treatment lasted 24 weeks, at the time when they were given their last appointment for final evaluation.

Intervention Type
Supplement

Primary outcome measure
1. Glucose (Cat. GL1611), glycosylated haemoglobin (Cat.HA3830A), total cholesterol (Cat. CHO215), HDL-cholesterol (Cat. CH3811A), LDL (Cat. CH3811B) & triacylglycerides (Cat. Tr213) are assessed using an ultrasensitive colorimetric method in an automated Selectra II equipment, with commercial RANDOX™ reactants. VLDL was calculated with the Friedwald equation (Friedwald et.al. 1972). All measurements were done at baseline and 24 weeks
2. Plasma fatty acids are measured using chromatography and methylation at baseline and 24 weeks
3. Vitamin D and insulin are measured using a commercial ELISA kit from R&D Systems (Cat. 51081) assay at baseline and 24 weeks
4. Cytokines are assessed using Milliplex Human Citokine Five Plex (Cat. MPXHCYTO-60K-05) for TNFα, IFN-γ, IL-1β, IL4 and IL10 and the Milliplex Human Citokine One Plex (Cat. MPXHCYTO-B-01) for TGF- β, at baseline and 24 weeks
5. Adipokines Adiponectin, Resistin and Leptin levels are assessed with the Milliplex Human Adipokine Magnetic Bead Panel (Cat.HADK1-61K-02 and Cat.HADK1-61K-01) at baseline and 24 weeks

Secondary outcome measures
1. Dietary intake is assessed through 24-hour dietary recall at baseline and every four weeks until the final evaluation at 24 weeks
2. Anthropometry (weight, height, BMI) is assessed with a portable stadiometer and weighing scale at baseline and 24 weeks
3. Treatment adherence is assessed with the Morinksey-Green and Haynes-Sackett tests every four weeks from baseline to week 24

Overall study start date
01/01/2014

Completion date
30/12/2016

Eligibility

Key inclusion criteria

1. Diagnosed type 2 diabetes mellitus
2. Age between 25 and 55 years
3. BMI ≥ 29.9
4. With no other chronic pathology
5. No insulin treatment
6. HOMA ≥ 2.4

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 patients divided into four groups

Key exclusion criteria
1. Pregnancy or lactation
2. Non-mixed Mexican origin (native or immigrants)
3. Lack of data from measurements

Date of first enrolment
01/03/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Mexico

Study participating centre
Faculty of Medicine, Universidad Autónoma del Estado de México
Paseo Tollocan esq. Jesús Carranza
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50180

Sponsor information

Organisation
Universidad Autonoma del Estado de Mexico

Sponsor details
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Sponsor type
University/education

Website
www.uaemex.mx

ROR
https://ror.org/0079gpv38

Funder(s)

Funder type
Government

Funder Name
Consejo Nacional de Ciencia y Tecnología (CONACyT)

Results and Publications

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

Intention to publish date
30/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Roxana Valdes-Ramos, DSc (Principal Investigator) rvaldesr@uaemex.mx

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/06/2017		Yes	No

Results article	results	11/07/2017	Yes	No