

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	☐ Prospectively registered ☐ Protocol
Registration date 24/10/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/07/2018	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Contact name

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Additional identifiers

Protocol serial number

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 Committees of the Faculty of Medicine of the Universidad Autónoma del Estado de México, 31/01/2013

Primary study design

Interventional

Study design

Placebo-controlled cluster randomised trial

Study type(s)

Prevention

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(s)

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 TNF α , IFN- γ , IL-1 β , 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

Key secondary outcome(s)

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

Completion date

30/12/2016

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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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Toluca

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Sponsor information**Organisation**

Universidad Autonoma del Estado de Mexico

ROR

<https://ror.org/0079gpv38>

Funder(s)**Funder type**

Government

Funder Name

Consejo Nacional de Ciencia y Tecnología (CONACyT)

Results and Publications

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