

Addition of eicosapentaenoic acid to maintenance anti-depressant therapy in diabetes patients with major depressive disorder: a double-blind, placebo-controlled pilot study

Submission date 28/04/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/02/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.diabetespsychology.nl/abstracts/omega-3.htm>

Contact information

Type(s)

Scientific

Contact name

Dr F. Pouwer

Contact details

VU University Medical Center
Department of Medical Psychology
Diabetes Psychology Research Group
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 4449679
f.pouwer@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

DFN 2004.13.004

Study information

Scientific Title

Study objectives

Addition of eicosapentaenoic acid (1 g/day) to maintenance anti-depressant therapy in diabetes patients with major depression will be associated with a reduction of depression symptoms, compared to placebo (1 g grapeseed oils).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of the VU Medical Centre, Amsterdam on the 15th September (ref: METC 2005/137)

Study design

Randomised placebo-controlled double blind trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Major depressive disorder

Interventions

Two capsules containing eicosapentaenoic acid (total amount of 1 g/day) or placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Eicosapentaenoic acid

Primary outcome measure

Depression

Secondary outcome measures

Glycaemic control

Overall study start date

01/04/2006

Completion date

01/04/2007

Eligibility

Key inclusion criteria

1. 18 - 75 years old
2. Having diabetes
3. Current diagnosis of major depressive disorder that is being treated with ongoing anti-depressant medication
4. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Psychotic features
2. History of (hypo)-mania
3. An average consumption of fish higher than two servings per week or current daily use of fish oil supplements
4. Active suicidal ideation or a history of suicide attempt

5. Allergy for fish or fish products

6. Pregnancy

Date of first enrolment

01/04/2006

Date of final enrolment

01/04/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

VU University Medical Center

Amsterdam

Netherlands

1081 BT

Sponsor information

Organisation

VU University Medical Center, EMGO-Institute (The Netherlands)

Sponsor details

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

+31 (0)20 4448180

emgo@vumc.nl

Sponsor type

University/education

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Industry

Funder Name

Dutch Diabetes Research Foundation (The Netherlands)

Alternative Name(s)

Dutch Diabetes Research Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Minami Nutrition Inc. (USA)

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	01/01/2012		Yes	No