ISRCTN30877831 https://doi.org/10.1186/ISRCTN30877831

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

Registration date
28/04/2006

Last Edited
27/02/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] 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
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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Depression

Key secondary outcome(s))
Glycaemic control

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes