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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28433

Bron
Nationaal Trial Register

Verkorte titel
Omega-3 fatty acid EPA for depression in diabetes

Aandoening

Major depression, diabetes

Ondersteuning

Primaire sponsor: Dutch Diabetes Research Foundation
Minami Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Depression.

Toelichting onderzoek

Achtergrond van het onderzoek

Depression can be regarded as a common threat to the quality of life of diabetes patients. Evidence strongly suggests that major depression is more prevalent and more persistent in diabetes patients compared to the general population. Depression in diabetes is also associated with impaired glycaemic control, an increased risk for cardiovascular complications and increased health care consumption. Effective pharmacological interventions are available to treat major depression. Yet, in only 50-60% of the depressed subjects with diabetes, pharmacotherapy does lead to remission of depression.

Both depression and diabetes were found to be associated with an impaired fatty acid metabolism. Several animal and epidemiological studies have found that consumption of omega-3 fatty acids is associated with a decreased risk for depression. Three randomised controlled trials in non-diabetic subjects demonstrated that omega-3 fatty acids as add-on therapy is effective in treating major depression, whereas one trial found that monotherapy with docosahexaenoic acid is not. So far, interventions in diabetes patients are lacking. The omega-3 fatty acids have three main advantages: 1) they are relatively inexpensive, 2) generally well tolerated by patients and 3) decrease the risk of cardiovascular disease. The available evidence warrants a trial with omega-3 PUFA in particular in the diabetic population, that has a high prevalence of treatment-resistant depression.
The currently proposed randomised double-blind, placebo-controlled pilot add-on study will be the first to test this hypothesis in diabetes patients suffering from current major depression and to determine underlying physiological mechanisms.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

2 capsules containing eicosapentaenoic acid (total amount of 1 gam/day) or placebo.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18-75 years old;

2. Having diabetes;

3. Current diagnosis of major depressive disorder that is being treated with ongoing anti-depressant medication; and

4. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Psychotic features;

2. History of (hypo) mania;

3. An average consumption of fish higher than 2 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2006
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-03-2006

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL568
NTR-old	NTR624
Ander register	: DFN 2004.13.004
ISRCTN	ISRCTN30877831

Resultaten

Samenvatting resultaten
N/A