Fluoxetine in progressive multiple sclerosis: A placebo-controlled randomized trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23448

Source
Nationaal Trial Register

Brief title
N/A

Health condition

multiple sclerosis

Sponsors and support

Primary sponsor: Multiple Sclerosis Internationaal
Source(s) of monetary or material Support: Innovatiefonds UMCG

Intervention

Outcome measures

Primary outcome

Number of patients with progression in two years. Progression is defined as:
1. Persistent (2 or more follow-up assessements) worsening of EDSS with 1.0 point with basis EDSS 3.0-5.0 or persistent (2 or more follow-up assessements) worsening of EDSS with 0.5

with basis EDSS 5.5-6.5;
2. Or persistent (2 or more follow-up assessements) worsening of 9-HPT with 20% compared to baseline measurement;
3. Or persistent (2 or more follow-up assessements) worsening of the AI of 1 point with a basis AI between 2 and 6.

Secondary outcome

1. Change in the folowing MRI measurements:
a. T2 lesion volume;
b. T1 lesion volume (black holes);
c. Brain atrophy;
d. NAA;
e. ADC and FA histogram values;
2. Change in EDSS, MSFC, SF-36, Guys Neurological Disability Scale, BDI, FIS;
3. Time (in months) to progression.

Study description

Background summary

In this placebo-controlled randomized trial, we study whether fluoxetine 40 mg/day is able to reduce progression in patients with multiple sclerosis after 2 years of treatment.

Study objective

Fluoxetine has in animals and cell cultures neuroprotective properties. We test whether fluoxetine is able to reduce progression in patients with multiple sclerosis.

Intervention

1. Treatment with fluoxetine 40 mg/day or placebo during 2 years;
2. Every 3 months clinical evaluation (EDSS, MSFC, AI);
3. Yearly cerebral MRI;
4. Yearly questionairres (Guys Neurological Disability Scale, BDI, SF-36).

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Eligibility criteria

Inclusion criteria

1. Written informed consent;
2. Age 18-65;
3. Multiple sclerosis (MS) according to the Mc Donald criteria or primary progressive MS according to the Thompson criteria;
4. EDSS 3.0-6.5 inclusive;
5. Documented progression in the last 2 year unrelated to clinical exacerbations in the last 2 year.

Exclusion criteria

1. Contra-indication MRI (eg. metal, claustrophobia);
2. Women of childbearing potential, who are not using a medically accepted safe method of contraception;
3. Pregnancy or women who are lactating;
4. Moderate to severe depression measured as a score > 18 on the Beck Depression Inventory;
5. Treatment with SSRI's;
6. Treatment with MAO-inhibitors, oral anticoagulantia,5-HT agonists and/or lithium;
7. Treatment with interferon ß, glatiramer acetate, plasmapheresis, natalizumab, other immunomodulatory drugs, or immunosuppressive drugs including azathioprine, cyclophosphamide and methotrexate, within 6 months of week 0;
8. Treatment with corticosteroids within 3 months of week 0;
9. Renal failure;
10. Neurological disorder other than MS, acute or chronic infection, malignant neoplasm or

metastasis, cardiovascular disorder or pulmonary disorder, severe intercurrent systemic disease, or any other disease that interferes with the assessments.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2006
Enrollment:	42
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-03-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL583
NTR-old	NTR639
Other	: N/A
ISRCTN	ISRCTN38456328

Study results

Summary results
N/A