

Fluoxetine in progressive multiple sclerosis: a placebo-controlled randomised trial

Submission date 15/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/01/2021	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NL583, NTR639

Study information

Scientific Title
Fluoxetine in progressive multiple sclerosis: a placebo-controlled randomised trial

Study objectives

Fluoxetine has in animals and cell cultures neuroprotective properties. We test whether fluoxetine is able to reduce progression in patients with Multiple Sclerosis (MS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Placebo controlled, randomised trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple Sclerosis (MS)

Interventions

1. Treatment with fluoxetine 40 mg/day or placebo during 2 years
2. Every 3 months clinical evaluation (EDSS, Multiple Sclerosis Functional Composite [MSFC], Ambulatory Index [AI])
3. Yearly cerebral MRI
4. Yearly questionnaires (Guys Neurological Disability Scale, BDI, Short Form [SF-36] health survey)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fluoxetine

Primary outcome(s)

Number of patients with progression in two years. Progression is defined as:

1. Persistent (two or more follow-up assessments) worsening of EDSS with 1.0 point with basis EDSS 3.0 to 5.0 or persistent (two or more follow-up assessments) worsening of EDSS with 0.5 with basis EDSS 5.5 to 6.5
2. Or persistent (two or more follow-up assessments) worsening of 9-Hole Peg Test (9-HPT) with 20% compared to baseline measurement
3. Or persistent (two or more follow-up assessments) worsening of the AI of one point with a basis AI between two and six

Key secondary outcome(s)

1. Change in the following MRI measurements:
 - a. T2 lesion volume

- b. T1 lesion volume (black holes)
- c. Brain atrophy
- d. N-Acetyl Aspartate (NAA)
- e. Apparent Diffusion Co-efficient (ADC) and Fractional Anisotropy (FA) histogram values
- 2. Change in EDSS, MSFC, SF-36, Guys Neurological Disability Scale, BDI, Family Intrusiveness Scale (FIS)
- 3. Time (in months) to progression

Completion date

01/05/2009

Eligibility

Key inclusion criteria

- 1. Written informed consent
- 2. Age 18 to 65
- 3. MS according to the McDonald criteria or primary progressive MS according to the Thompson criteria
- 4. Expanded Disability Status Scale (EDSS) 3.0 to 6.5 inclusive
- 5. Documented progression in the last two years unrelated to clinical exacerbations in the last two years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

42

Key exclusion criteria

- 1. Contra-indication Magnetic Resonance Imaging (MRI) (e.g., 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 of more than 18 on the Beck Depression Inventory (BDI)
- 5. Treatment with Selective Serotonin Reuptake Inhibitors (SSRIs)
- 6. Treatment with Monoamine Oxidase (MAO)-inhibitors, oral anticoagulants, Serotonin (5-HT)

agonists and/or lithium

7. Treatment with interferon β , glatiramer acetate, plasmapheresis, natalizumab, other immunomodulatory drugs, or immunosuppressive drugs including azathioprine, cyclophosphamide and methotrexate, within six months of week zero

8. Treatment with corticosteroids within three months of week zero

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

Date of first enrolment

01/05/2006

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen (UMCG)

Groningen

Netherlands

9700 RB

Sponsor information

Organisation

University Medical Center Groningen (UMCG) (The Netherlands)

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Innovatiefonds University Medical Center Groningen (The Netherlands)

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	29/07/2013	06/01/2021	Yes	No