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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
15/09/2006		Protocol		
Registration date 15/09/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
07/01/2021	Nervous System Diseases			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

- 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

Overall study start date

01/05/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Total final enrolment

42

Kev 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 ß, 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)

Sponsor details

PO Box 30001 Groningen Netherlands 9700 RB

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/03cv38k47

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Innovatiefonds University Medical Center Groningen (The Netherlands)

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