ISRCTN38456328 https://doi.org/10.1186/ISRCTN38456328

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

Submission date	Recruitment status
15/09/2006	No longer recruiting
Registration date	**Overall study status**
15/09/2006	Completed
Last Edited	**Condition category**
07/01/2021	Nervous System Diseases

[ ] 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

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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

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 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
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Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

Sponsor details
PO Box 30001
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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