

Influence of long term administration of fluoxetine on cerebral threshold and muscle activation patterns in chronic stroke

Submission date 28/12/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/02/2007	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Acronym

flu2006

Study objectives

1. Long term use of fluoxetine causes the excitability of the primary motor area of the brain to change
2. Long term administration of fluoxetine causes the muscle activation patterns to change

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethics committee of Medisch Spectrum Twente (Enschede, The Netherlands) on the 7th February 2007 (ref: P06-53).

Study design

Randomised, placebo controlled, parallel group, double blinded 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

Stroke

Interventions

20 mg of fluoxetine during 12 weeks versus placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Fluoxetine

Primary outcome measure

1. Excitability of the primary motor area, measured by motor threshold and stimulus response curve
2. Muscle activation, measured by calculating Root Mean Square (RMS) during isometric and dynamic movements

Secondary outcome measures

1. Brain activation patterns
2. Phase synchronisation of the brain
3. Motor function

Overall study start date

01/01/2007

Completion date

31/12/2008

Eligibility**Key inclusion criteria**

1. Chronic ischaemic stroke patients (more than six months after stroke)
2. Aged over 18

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

28

Key exclusion criteria

1. Patients suffering from another neurological disease
2. Uncompensated hemineglect or cognitive disabilities
3. Epilepsy, or first epileptic insult post stroke
4. Patients with first grade relatives suffering from epilepsy
5. Pregnancy
6. Pacemaker
7. Pathological heart rhythms disorders
8. Use of anti-depressants

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Rehabilitation Centre 'The Roessingh' Enschede

Enschede

Netherlands

7500 AH

Sponsor information

Organisation

Rehabilitation Centre 'The Roessingh' Enschede (The Netherlands)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.rrd.nl/www/indexa.html>

ROR

<https://ror.org/02nmj4h80>

Funder(s)

Funder type

Research organisation

Funder Name

St. Jorisstichting (The Netherlands)

Funder Name

Ridderlijke Duitse Order (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