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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 16/02/2007	**Condition category** Circulatory System	

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
1

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).

Primary study design
Interventional

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
1. Brain activation patterns
2. Phase synchronisation of the brain
3. Motor function

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

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)

ROR
https://ror.org/02nmj4h80

Funder(s)

Funder type
Research organisation

Funder Name
St. Jorisstichting (The Netherlands)

Funder Name
Ridderlijke Duitsche Order (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration