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Influence of a single dose of fluoxetine on muscle activation patterns and functional ability in chronic stroke patients

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/12/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/05/2009	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
NTR220

Study information

Scientific Title

Study objectives
A single dose of fluoxetine influences muscle activation patterns and functional ability of the muscles in the lower part of the upper extremity in chronic stroke patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised double blind placebo controlled crossover 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
Ischaemic stroke

Interventions
Single administration of 20 mg of fluoxetine, or placebo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Fluoxetine

Primary outcome measure
Muscle activation patterns, measured by electromyogram (EMG).

Secondary outcome measures
1. Grip strength
2. Motricity Index
3. Delay times

Overall study start date
11/03/2004

Completion date
01/11/2004

Eligibility

Key inclusion criteria
The participating patients suffered a single ischemic stroke (confirmed by CT-scan or MRI-scan) more than six months before the start of the trial, they were over 18 years of age. Furthermore, they were able to perform some selective movements with the paretic wrist (MRC 2). And were able to follow the instructions they were given.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Patients suffering from an other neurological disease
2. Uncompensated hemineglect or cognitive disabilities, resulting in misunderstanding or incapability of executing instructions given
3. Epilepsy, or first epileptic insult post stroke
4. Patients with first grade relatives suffering epilepsy
5. Pregnancy
6. Pacemaker
7. State after irritation or lesion of median nerve
8. Implanted pumps to administer medicines
9. Metal parts inside the head
10.Cerebral aneurysm-clips (metal inside)
11. Uncontrolled medical problems
12. Alcoholism or drug-use

13. Pathological heart rhythm disorders
14. Raised intracerebral pressure (hydrocephalus)
15. External catheter

Date of first enrolment
11/03/2004

Date of final enrolment
01/11/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
P.O. Box 310
Enschede
Netherlands
7500 AH

Sponsor information

Organisation
Roessingh Research and Development (Netherlands)

Sponsor details
Roessingh Rehabilitation Centre
P.O. Box 310
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m.ijzerman@rrd.nl

Sponsor type
Hospital/treatment centre

Website
http://www.rrd.nl/

ROR
https://ror.org/01dmjt679

Funder(s)

Funder type
Research organisation

Funder Name
Euregio - INTERREG IIIA programme (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