

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

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| Submission date 20/12/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 20/12/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 15/05/2009 | 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

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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

Enschede

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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