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

Submission date	Recruitment status	Prospectively registered
20/12/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2005	Completed	Results
Last Edited	Condition category	Individual participant data
15/05/2009	Circulatory System	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

Protocol serial number 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

Study type(s)

Treatment

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(s)

Muscle activation patterns, measured by electromyogram (EMG).

Key secondary outcome(s))

- 1. Grip strength
- 2. Motricity Index
- 3. Delay times

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

https://ror.org/01dmjt679

Funder(s)

Funder type

Research organisation

Funder Name

Euregio - INTERREG IIIA programme (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration