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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20685

Source
NTR

Brief title
flu2006

Intervention

Outcome measures

Primary outcome

excitability of the primary motor area, measured by motor threshold and stimulus response curve;
muscle activation, measured by calculating RMS during isometric and dynamic movements

Secondary outcome

brain activation patterns;
phase synchronization of the brain;
motor function

Study description

Background summary

Stroke is one of the major causes of disability in developed countries. After stroke most patients suffer from hemiparesis, and especially the distal parts of the body are affected. Even after intensive training many patients still suffer from motor impairment. Previous studies have been done examining the possibility of improving motor recovery by studying the effects of neuropharmaca.
One neuropharmaca of which the effects are studied before are selective serotonin reuptake inhibitors (SSRIs). However, inconsistent results were found, as some studies found an improved motor function, while other studies did not found any effect at all. Most of these studies only measured motor function.
Several, more sensitive, variables are correlated with motor function. This study examines the effects of fluoxetine (an SSRI) on these variables. As changes in these parameters will possibly explain why fluoxetine could improve motor function.
Primary objective of the study is to measure the effects of long term fluoxetine administration on brain excitability and muscle activity.
Hypotheses are: (1) long-term use of fluoxetine causes the excitability of the primary motor area of the brain to change; and (2) Long-term administration of fluoxetine causes the muscle activation patterns to increase. Also some secondary hypotheses will be measured: (3) Long-term use of fluoxetine modulates activation of areas in the brain during voluntary movement; (4) Long-term administration of fluoxetine increase the communication between areas in the brain; (5) Long-term administration of fluoxetine causes the motor function to change.
The primary study parameters are: motor threshold, and stimulus response curve (SRC) to measure excitability of the brain, and the root mean square (RMS) of the electromyogram (EMG) during movement of the lower part of the arm, to measure muscle activation.
Secondary study parameters are: activation of frequencybands in the brain, phase-synchronization in the brain to measure communication between different areas, and the Fugl-Meyer score, and grip strength to measure motor function.
The study design is a doubleblind placebo controlled study.
Twenty-eight chronic stroke patients will be included. They have to be over the age of 18. Fourteen patients will receive one tablet containing 20 mg of fluoxetine every day, during 12 weeks. The other 14 patients will receive a placebo for 12 weeks.
The patients are asked to come to the research centre for four times (start of the trial, and after 6, 12 and 20 weeks). Every time all parameters will be measured. Also a depression questionnaire has to be answered to control the group for signs of depression. In the 6th week a blood sample will be taken.

Study objective

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

Intervention

20 mg of fluoxetine during 12 weeks

Contacts

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Eligibility criteria

Inclusion criteria

Chronic ischemic stroke patients (> 6 months after stroke); age > 18

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 antidepressants

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	28
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL764
NTR-old	NTR775
Other	: 1
ISRCTN	ISRCTN46063747

Study results

Summary results
N/A