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

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Objective of the study is to measure the effects of long term fluoxetine administration on brain- and muscle activity in combination with the effects on motor function. Main questions are:(1) Influences long-term administration of fluoxetine...

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON30510

Source
ToetsingOnline

Brief title
Influence of fluoxetine on brain and muscle activity in stroke patients

Condition

- Central nervous system vascular disorders

Synonym
cerebral vascular accident, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brain activity, fluoxetine, muscle activity, Stroke

Outcome measures

Primary outcome

Primary study parameters are:

- Motor threshold (MT) to measure excitability

- stimulus response curve (SRC) to measure excitability

- root mean square (RMS) of the electromyogram (EMG) of the lower part of the

arm, to measure muscle activation.

Secondary outcome

Secundary study paramters are:

- activation of frequencybands in the brain;

- phase-synchronization in the brain, to measure communication between

different areas;

- 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 mainly the distal parts of the body are affected. Even after intensive training many patients still suffer from motor impairment. One
Previous studies have been done examining the effects of neuropharmaca on motor recovery.
One neuropharmaca of which the effect is 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 effects. These studies only measured motor function.
While several fundamental variables are correlated with a changed motor function, this study examines the effects of fluoxetine (SSRI) on these variables and relates these changes to motor function. This will possibly explain why fluoxetine could improve motor function. Hypotheses are: (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 increase; (3)Long-term use of fluoxetine modulates activation of areas in the brain during voluntary movement; (4) Long-term administration of lfuoxetine increase the communication between areas of the brain; (5) Long-term administration of fluoxetine causes the motor function to change.

Study objective

Objective of the study is to measure the effects of long term fluoxetine administration on brain- and muscle activity in combination with the effects on motor function.
Main questions are:
(1) Influences long-term administration of fluoxetine excitability of the primary motor cortex of the brain?
(2) Does long-term administration of fluoxetine increase the muscle activation patterns?

Secondary questions are:
(3) Influences long term administration of fluoxetine activity patterns in the brain?
(4) Does communication between areas in the brain improve after long term administration of fluoxetine?
(5) Does motor function improve after long term administration of fluoxetine?

Study design

Doubleblind placebo controlled study

Intervention

17 Patients have to administer one tablet containing 20 mg of fluoxetine every day during 12 weeks. The other 17 patients receive one tablet of placebo every day.

Study burden and risks

Therapeutic risks of the current study, are the side effects of fluoxetine.
These side effects are mostly nausea and restlessness. However some harsh side

effects, like serotoninesyndrom, occur rarely. All reported side effects are mentioned in the IB.

Non-therapeutic risk comes from the use of transcranial magnetic stimulation (TMS) which is used to measure brain excitability. A rarely occuring side effect is the activation of an epileptic insult.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

First ever ischemic cortical/subcortical ischemic stroke, confirmed by CT or MRI; more than 6 months after stroke; age > 18

Exclusion criteria

Patients suffering from another neurological disease; uncompensated hemineglect or cognitive disabilities; epilepsy, or first epileptic insult post stroke; patients with first grade relatives suffering from epilepsy; pregnancy; pacemaker; pathological heart rhythms disorders; use of antidepressants.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	34
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Fluoxetine
Generic name:	Fluoxetine

Ethics review

Approved WMO

Date:	10-11-2006
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-02-2007
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
EudraCT	EUCTR2006-005044-86-NL
CCMO	NL14459.044.06