Influence of a single dose of fluoxetine on brain activity during movement observation and execution, muscle activity and motor function in chronic stroke patients.

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The objective of this study is to examine the influence of a single dose of fluoxetine and of movement observation on cortical activity, and to relate the changes of the activity of the brain to muscle activation, motor function and motor control in...

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

Summary

ID

NL-OMON33575

Source
ToetsingOnline

Brief title
Influence of fluoxetine on brain activity during movement (observation)

Condition

- Central nervous system vascular disorders

Synonym
stroke or CVA

Research involving
Human

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: Interreg Euregio

Intervention

Keyword: brain activity, fluoxetine, motor function, stroke

Outcome measures

Primary outcome

The main study parameter is the change in cortical activity after administration of fluoxetine and during movement observation. Secondary parameters are muscle activation patterns and motor outcomes (Fugl-Meyer and force). The changes of brain activity will be correlated with the changes in muscle activity and motor outcome. The changes of muscle activity will also be correlated with those in motor outcome.

Secondary outcome

Secondary parameters are muscle activation patterns and motor outcomes (Fugl-Meyer and force). The changes of brain activity will be correlated with the changes in muscle activity and motor outcome. The changes of muscle activity will also be correlated with those in motor outcome.

Study description

Background summary

The goal of this study is to understand the effect of fluoxetine on rehabilitation after stroke and the role of movement observation in this process. Changes of cortical activity during observation and during execution of a movement and muscle activation patterns during wrist movements after intake of fluoxetine and placebo will be measured and compared, and will also

be correlated to motor outcome.

Study objective

The objective of this study is to examine the influence of a single dose of fluoxetine and of movement observation on cortical activity, and to relate the changes of the activity of the brain to muscle activation, motor function and motor control in chronic stroke patients.

Study design

The study is a double-blind, randomized, placebo-controlled, cross-over design.

Intervention

The intervention consists of the administration of a single dose of 20 mg fluoxetine on one day and the administration of placebo on the other day to all participants.

Study burden and risks

The patients need to come to Roessingh R&D on two days which are 14 days apart. The non-invasive measurements will take 1 hour in the morning and 1.75 hours in the afternoon. Patients have to stay at the RRD, or Het Roessingh between the measurements on one day. Therefore, the total time for the patient is 7.5 hours on each of the 2 days.
All measurements consist of the Fugl-Meyer motor assessment, EMG of two muscles of the lower arm and a recording of force of these muscles. The afternoon measurements also include a 64-channel EEG measurement. The EEG will be measured during eyes open, eyes closed, movement observation and movement execution. These measurements will be performed twice a day, five hours apart. In between, the patient will receive a capsule with a single dose of 20 mg fluoxetine on one day and a placebo capsule on the other measurement day. The risk of participation in this study is low. Personal benefit of participation is not to be expected.

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

minimal six months post-stroke
first-ever stroke
unilateral and/or subcortical stroke
age between 18 and 80 years
some motor dysfunction of the arm/hand but some remaining motor function (MRC between 2 and 4)
obtained informed consent

Exclusion criteria

other (pre-existing) neurological diseases (e.g. epilepsy, tumor, paralysis)
known allergy to SSRI*s
use of anti-depressants (tricyclic antidepressants, serotonin reuptake inhibitors, MAO-inhibitors)
autism spectrum disorders, PDD, schizophrenia (or history of schizophrenia)
instable medical health situation (cardiovascular and/or neurological)
uncompensated hemineglect or cognitive disabilities, resulting in misunderstanding or incapability of executing instructions given
uncorrected visual problems, i.e. not able to observe the movie on the screen
pregnancy

severe uncontrolled medical conditions
known alcoholism or drug abuse
known elevated brain pressure (hydrocephalus)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	fluoxetine
Generic name:	fluoxetine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	04-06-2008
Application type:	First submission

Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-09-2008
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	11-02-2010
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	16-02-2010
Application type:	Amendment
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	EUCTR2008-003349-97-NL
CCMO	NL23063.044.08