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

No registrations found.

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

Summary

ID

NL-OMON26776

Source
NTR

Brief title
flu2008

Health condition

stroke

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

- EEG after fluoxetine intake and during movement observation

Secondary outcome

- Fugl-Meyer motor assessment, EMG, force production

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.

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.

The study is a double-blind, randomized, placebo-controlled, cross-over design.
Twenty chronic stroke patients (>6 months post-stroke), between 18 and 80 years old with an MRC between 2 and 4 will be recruited for this study.

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.

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.

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.

Study objective

Fluoxetine and movement observation are able to increase cortical activity after stroke

Study design

Measurements are two weeks apart

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.

Contacts

Public
Roessingh Research and Development
Rehabilitation Centre
P.O. Box 310
H.I. Genderen, van
Roessingbleekweg 33B

Enschede 7500 AH
The Netherlands
+31 (0)53 4875765
Scientific
Roessingh Research and Development
Rehabilitation Centre
P.O. Box 310
H.I. Genderen, van
Roessingbleekweg 33B

Enschede 7500 AH
The Netherlands
+31 (0)53 4875765

Eligibility criteria

Inclusion criteria

1. First ever ischemic stroke, confirmed with a CT-scan or MRI-scan

2. Unilateral cortical and/or subcortical stroke

3. Stroke more than 6 months ago

4. Some motor dysfunction of the arm/hand but some motor function left (MRC between 2 and 4)

5. Age between 18 and 80 years

6. Obtained informed consent

Exclusion criteria

1. Other (pre-existing) neurological diseases (e.g. epilepsy, tumor, paralysis)

2. Known allergy to SSRI’s

3. Use of anti-depressants (tricyclic antidepressants, serotonin reuptake inhibitors, MAO-inhibitors)

4. Autism spectrum disorders, PDD, schizophrenia (or history of schizophrenia)

5. Unstable medical health situation (cardiovascular and/or neurological)

6. Uncompensated hemineglect or cognitive disabilities, resulting in misunderstanding or incapability of executing instructions given

7. Uncorrected visual problems, i.e. not able to observe the movie on the screen

8. Pregnancy

9. Breastfeeding

10. Known kidney dysfunctions

11. Severe uncontrolled medical conditions

12. Known alcoholism or drug abuse

13. Known elevated brain pressure (hydrocephalus)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	20
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	NL675
NTR-old	NTR1377
Other	Roessingh Research & Development : 08-22
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A