

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

<b>Submission date</b> 28/12/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/02/2007	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

## Acronym

flu2006

## Study objectives

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

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the Medical Ethics committee of Medisch Spectrum Twente (Enschede, The Netherlands) on the 7th February 2007 (ref: P06-53).

## Study design

Randomised, placebo controlled, parallel group, double blinded trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Stroke

## Interventions

20 mg of fluoxetine during 12 weeks versus placebo.

## Intervention Type

Drug

## Phase

Not Specified

**Drug/device/biological/vaccine name(s)**

Fluoxetine

**Primary outcome measure**

1. Excitability of the primary motor area, measured by motor threshold and stimulus response curve
2. Muscle activation, measured by calculating Root Mean Square (RMS) during isometric and dynamic movements

**Secondary outcome measures**

1. Brain activation patterns
2. Phase synchronisation of the brain
3. Motor function

**Overall study start date**

01/01/2007

**Completion date**

31/12/2008

**Eligibility****Key inclusion criteria**

1. Chronic ischaemic stroke patients (more than six months after stroke)
2. Aged over 18

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

28

**Key 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 anti-depressants

**Date of first enrolment**

01/01/2007

**Date of final enrolment**

31/12/2008

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Rehabilitation Centre 'The Roessingh' Enschede

Enschede

Netherlands

7500 AH

## **Sponsor information**

**Organisation**

Rehabilitation Centre 'The Roessingh' Enschede (The Netherlands)

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://www.rrd.nl/www/indexa.html>

**ROR**

<https://ror.org/02nmj4h80>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

St. Jorisstichting (The Netherlands)

**Funder Name**

Ridderlijke Duitsche Order (The Netherlands)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration