Interaction between the brain hemispheres - key to motor recovery after stroke (InterAct)

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The aim of this study is to determine whether cTBS treatment of the contralesional primary motor cortex leads to a reduction in contralesional inhibition from the contralesional to the ipsilesional motor cortex during movement onset.

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

Summary

ID

NL-OMON56847

Source
ToetsingOnline

Brief title
InterAct

Condition

- Central nervous system vascular disorders

Synonym
Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: electrophysiology, Interhemispheric inhibition, Stroke, Transcranial magnetic stimulation

Outcome measures

Primary outcome

Premovement interhemispheric inhibition from the contralesional to the

ipsilesional primary motor cortex.

Secondary outcome

Interhemispheric inhibition from the contralesional to the ipsilesional primary

motor cortex at rest

TMS interference of the contralesional primairy motor cortex

Intracortical inhibition of the contralesional primairy motor cortex (optional)

Study description

Background summary

Many stroke patients suffer from upper limb impairment and do not recover completely. Previous studies show that motor impairment is associated with disrupted activity in the motor areas of the brain. Non-invasive brain stimulation techniques, such as transcranial magnetic stimulation (TMS), can be used to influence brain activity and facilitate the recovery of motor function in patients with stroke. Research from the UMC Utrecht (B-STARS study) showed that continuous theta burst stimulation (cTBS), an inhibitory form of rTMS, promotes recovery of the upper limb. However, the response to treatment varies substantially between patients and little is known about the working principle of cTBS treatment. Improved understanding of the working mechanism can be used to select patients who benefit from cTBS treatment.

Study objective

The aim of this study is to determine whether cTBS treatment of the contralesional primary motor cortex leads to a reduction in contralesional inhibition from the contralesional to the ipsilesional motor cortex during

movement onset.

Study design

A prospective open-label intervention study

Intervention

cTBS treatment of the contralesional primary motor cortex

Study burden and risks

The risk of participation in this study is negligible. The side effects of TMS consist of headache (<4%) and neck pain (<1%) and the risk of an epileptic seizure is very rare (0.02%). Some patients may experience claustrophobia, dizziness, headache, nausea or sensory sensations during MRI. We are aware of the burden on patients when they undergo these diagnostic procedures in an early stage of recovery. However, these data can provide valuable insight on post-stroke motor recovery and the role neuromodulation treatment in stroke patients, which can potentially be used to individualize and improve future rehabilitation treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:
- Age, 18 years or older;
- First-ever unilateral ischemic stroke or intracerebral hemorrhage in a cerebral hemisphere or the brainstem;
- Unilateral upper limb paresis with a motricity index between 9 and 99;
- Inclusion possible between 3 weeks and 6 weeks after stroke onset;
- Signed informed consent.
In order to be eligible to participate in this study, a healthy control must meet all of the following criteria:
- Age >= 18 years;
- Normal motor function with a minimum Motricity Index (MI) of 99;
- Signed informed consent.

Exclusion criteria

- Upper limb paresis prior to stroke onset;
- Absolute contra-indication to TMS: Magnetic sensitive objects implanted in the head or neck area (e.g. cochlear implants, implanted neurostimulator, pacemaker or defibrillator, metal splinters, metal fragments or metal clips), history of epilepsy, pregnancy or other contra-indications that may potentially be harmful as determined by the treating rehabilitation physician;
- Incompetence or severe impairments that can impede study participation as determined by the treating rehabilitation physician (i.e. extreme fatigue, severe communication deficits);
- Life expectancy shorter than one year.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-10-2024
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Transcranial magnetic stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-07-2024
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-12-2024
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL86587.041.24