

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation a new therapeutic approach to improve motor function of upper limb in hemiplegia patients based on combination external repetitive trans magnetic brain stimulation and tracking exercises with modified joy stick

Protocol summary

Summary

Inclusion criteria: hemiplegia in dominant and spastic hand; at least 2 months after stroke; modified ashword scale 2-3; men and women with stroke in the age range 30-65; normal vision in perimetry test; MMSE score above 10 and NIHSS score 7-15; range of motion in wrist and elbow Exclusion criteria: stroke origin heart emboli; heart pace maker and arrhythmia; fracture in upper limb; neurologic diseases such as Parkinson disease, Multiple Sclerosis and epilepsy; implant in skull; problem in occipital, limbic system and complementary area and unable to accompany for 4 weeks Purpose: Recent studies have shown effects of rTMS 1 Hz and joy stick on improve hand function of patients with stroke. The aim of this study is compare of the effect of combination of rTMS and joy stick simultaneously on the wrist and elbow joints movements and compare the results with use of magnetic stimulation, tracking exercise with joy stick and routine physical therapy. Design: Not blinded. Methods: Patients will be randomly divided into 4 groups and receive 10 sessions 70 minutes treatment, 4 sessions per week. Participants: Men and women with stroke in the age range 30-65, at least 2 months after stroke, with no cardiac source of embolism, heart pace maker and arrhythmia, Epilepsy and implant in skull. Interventions: 4 treatment groups consist of minutes routine rehabilitation(upper limb exercise therapy), treatment with rTMS 1 Hz, treatment with joy stick and treatment with combination of rTMS and joy stick, will treated for 10 sessions 70 minutes treatment, 4 sessions per week. Variables: Improvement of involved hand function, grip force, range of motion, spasticity, accuracy, time and distance of test will measured.

General information

Acronym

Trans magnetic stimulation and stroke

IRCT registration information

IRCT registration number: **IRCT201111088027N1**

Registration date: **2011-12-20, 1390/09/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-12-20, 1390/09/29

Registrant information

Name

Poopak Moatamed Vaziri

Name of organization / entity

Pardis Physical Therapy Center

Country

Iran (Islamic Republic of)

Phone

+98 8844335488424094

Email address

poopakmoatamedv@yahoo.com

Recruitment status

Recruitment complete

Funding source

Pardis Physical Therapy Center

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation a new therapeutic approach to improve motor function of upper limb in hemiplegia patients based on combination external repetitive trans magnetic brain stimulation and tracking exercises with modified joy stick

Public title
The effect of trans magnetic stimulation to improve motor function of upper limb in hemiplegia patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: hemiplegia in dominant and spastic hand; at least 2 months after stroke; modified ashword scale 2-3; men and women with stroke in the age range 30-65; normal vision in perimetry test; MMSE score above10 and NIHSS score 7-15; range of motion in wrist and elbow Exclusion criteria: stroke origin heart emboli; heart pace maker and arrhythmia; fracture in upper limb; neurologic diseases such as Parkinson disease, Multiple Sclerosis and epilepsy; implant in skull; problem in occipital, limbic system and complementary area and unable to accompany for 4 weeks

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tarbiat Modares University
Street address

Medical Sciences Department- Jalale ale ahmad
avenue
City
Tehren
Postal code
175-14115
Approval date
2011-01-10, 1389/10/20
Ethics committee reference number
52/84482

Health conditions studied

1

Description of health condition studied
Stroke
ICD-10 code
G46*
ICD-10 code description
Vascular syndromes of brain in cerebrovascular diseases

Primary outcomes

1

Description
Improve grip force of involve hand
Timepoint
Pre and post of treatment
Method of measurement
Dynamometer

2

Description
Improve function of involve hand
Timepoint
Pre and post of treatment
Method of measurement
Fugle myer score- barthel score- NIHSS score

3

Description
Improve range of motion of joints of involve hand
Timepoint
Pre and post of treatment
Method of measurement
Wrist robo hab

4

Description
Improve spasticity of involve hand
Timepoint
Pre and post of treatment
Method of measurement
Wrist robo hab

5

Description

Improve accuracy, time and distance of test in involve hand

Timepoint

Pre and post of treatment

Method of measurement

Joy stick

Secondary outcomes

empty

Intervention groups

1

Description

10 sessions 70 minutes treatment, 4 sessions per week
Group 1(control): Per session, 30 minutes routine rehabilitation(upper limb exercise therapy), 20 minutes sham rTMS, 20 minutes exercise with sham joy stick

Category

Rehabilitation

2

Description

10 sessions 70 minutes treatment, 4 sessions per week
Group 2: Per session, 30 minutes routine rehabilitation(upper limb exercise therapy), 20 minutes rTMS 1 Hz on M1 of healthy hemisphere, 20 minutes exercise with sham joy stick

Category

Rehabilitation

3

Description

10 sessions 70 minutes treatment, 4 sessions per week
Group 3: Per session, 30 minutes routine rehabilitation(upper limb exercise therapy), 20 minutes sham rTMS, 20 minutes exercise by joy stick in front of monitor and drawing the different charts.

Category

Rehabilitation

4

Description

10 sessions 70 minutes treatment, 4 sessions per week
Group 4: Per session, 30 minutes routine rehabilitation(upper limb exercise therapy), 20 minutes rTMS 1 Hz on M1 of healthy hemisphere, 20 minutes exercise by joy stick in front of monitor and drawing the different charts

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Poopak Moatamed Vaziri

Street address

First floor, Number 3, kakuti alley, Shariati street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pardis Physical Therapy Center

Full name of responsible person

Morteza Noorii

Street address

First floor- Number 3- Kakuti alley- Shariati street

City

Tehran

Grant name

-

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pardis Physical Therapy Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Pardis Physical Therapy Center

Full name of responsible person

Poopak Moatamed Vaziri

Position

PhD

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty