Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The effect of combined rehabilitation based on visuo-perceptual and galvanic vestibular stimulation on balance function and brain waves of patients with right hemisphere ischemic stroke

Protocol summary

Study aim
Assessing the effect of combined rehabilitation based on visuo-perceptual and galvanic vestibular stimulation on balance function and brain waves in patients with right hemisphere ischemic stroke

Design
A controlled clinical trial with parallel groups, randomized using hexagonal block on 45 stroke patients

Settings and conduct
Patients with right hemisphere stroke with an individual complaint of imbalance in Rofideh Rehabilitation Hospital undergo vertical vision perception (SVV), status and electroencephalography assessments. Then they are divided into different groups and undergo galvanic atrial rehabilitation and RCDM for 10 sessions. At the end of the rehabilitation period and one month later, the evaluations are repeated.

Participants/Inclusion and exclusion criteria
Age range 40 to 60 years; Having a stroke for the first time in a year; No peripheral vestibular disorders; Difficulty balancing and walking; Ability to stand without assistance for at least 30 seconds; Right-handed.

Intervention groups
Group A (control): Stroke patients receiving conventional rehabilitation. Group B (intervention): Stroke patients receiving RCDM and sham galvanic rehabilitation. Group C (intervention): Stroke patients receiving combined galvanic and RCDM rehabilitation.

Main outcome variables
Changing the vertical perception of vision, Change the balance, Altered brain activity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201116049417N1**
Registration date: **2020-12-25, 1399/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-25, 1399/10/05**
Update count: **0**

Registration date
2020-12-25, 1399/10/05

Registrant information
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Meymaneh Jafari
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-12-05, 1399/09/15
Expected recruitment end date
2021-07-06, 1400/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of combined rehabilitation based on visuo-perceptual and galvanic vestibular stimulation on balance function and brain waves of patients with right

hemisphere ischemic stroke

Public title
The combined rehabilitation at cerebral stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ischemic stroke for the first time Confirmation of right hemisphere stroke with clinical evaluation and MRI imaging Having a stroke more than 2 weeks and less than a year before the start of the study Ability to understand oral commands Awareness of self, place and time Difficulty in balance and walking Stable medical condition Ability to stand independently without assistance for at least 30 seconds Ability to walk with or without aid for at least 15 meters Good visual acuity with proper correction Right-handed Appropriate cognitive status and earning a minimum of 19 points using MMSE
Exclusion criteria:
Cerebellar and orthopedic injuries Existence of neurological problems other than stroke The difference in the length of the two legs is more than 2 cm Use of drugs that impair vestibular function Peripheral vestibular disorders confirmed by VNG, vHIT and VEMP assessments History of BPPV Use of a heart pacemaker, metal brain implants, epilepsy or skin allergies behind the corners Recurrent strokes Any uncontrolled health condition in which assessments are prohibited
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, block randomization method was used for random allocation. The statistician designs 8 blocks of 6 (considering that we have 3 groups) using the "sealedenvelope.com" website. Blocking and allocation sequencing for concealment will be done by the person not involved in the research. The sample allocation ratio will be (Allocation 1: 1) and fall into three groups. Rehabilitation exercises will then be given to patients based on the obtained blocks and in the order of allocation sequence.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of University of Social Welfare and Rehabilitation Sciences
Street address
Kodakyar Ave., Daneshjo Blvd., Evin (Velenjak)
City
Tehran
Province
Tehran
Postal code
1985713871
Approval date
2019-10-21, 1398/07/29
Ethics committee reference number
IR.USWR.REC.1398.118

Health conditions studied

1

Description of health condition studied
Right hemisphere ischemic stroke
ICD-10 code
I61.1
ICD-10 code description
Nontraumatic intracerebral hemorrhage in hemisphere, cortical

Primary outcomes

1

Description
Score of Balance Systems Assessment Questionnaire (BESTest)
Timepoint
Before starting rehabilitation, Immediately after completion of rehabilitation, One month after the end of rehabilitation
Method of measurement
Using the BESTest questionnaire

2

Description
Score of POMA Balance and Gait Evaluation Questionnaire
Timepoint
Before starting rehabilitation, Immediately after completion of rehabilitation, One month after the end of rehabilitation
Method of measurement
Using the POMA questionnaire

3

Description
LOS range of motion
Timepoint
Before starting rehabilitation, Immediately after completion of rehabilitation, One month after the end of rehabilitation
Method of measurement
Using posturography

4

Description
SOT composite score
Timepoint
Before starting rehabilitation, Immediately after completion of rehabilitation, One month after the end of rehabilitation
Method of measurement
Using posturography

5

Description
Fixed error and absolute error of vertical vision perception (SVV)
Timepoint
Before starting rehabilitation, Immediately after completion of rehabilitation, One month after the end of rehabilitation
Method of measurement
Using SVV test

6

Description
DTABR and BSI in electroencephalography
Timepoint
Before starting rehabilitation, Immediately after completion of rehabilitation, One month after the end of rehabilitation
Method of measurement
Using Electroencephalography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sham vestibular galvanic stimulation for 20 minutes (providing stimulation at the beginning and turning off the stimulus), 2- Performing RCDM rehabilitation (perpendicularity of the line in the optokinetic field of view) for 20 minutes. This process is repeated during 20 sessions.Community Verified icon
Category
Rehabilitation

2

Description
Intervention group: 1- Presenting galvanic vestibular stimulation for 20 minutes at the threshold level and 2- Performing RCDM (perpendicular line in the optokinetic field of view) rehabilitation for 20 minutes. This process is repeated during 20 sessions.
Category
Rehabilitation

3

Description
Control group: Stroke patients receiving conventional physiotherapy rehabilitation: According to studies, range of motion exercises related to the upper and lower limbs, weight lifting on the involved side, walking in parallel load forward and backward, pelvic bridging exercises and stretching exercises.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rifeideh rehabilitation hospital
Full name of responsible person
Dr. Saeideh Mehrkian
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Nemati Aly, South Salimi Ave. Andarzgou Blv.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr. Hamidreza KhorramKhorshid
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Grant name

Grant code / Reference number

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

Title of funding source
University of social welfare and rehabilitation sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Meymaneh Jafari
Position
Phd candidate
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document

All potential data can be shared after de-identifying individuals.

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

The data of this study will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Further analysis of the delivered data will be possible only with the coordination of the main researcher.

From where data/document is obtainable

Applicants can submit their application by sending an email to the lead researcher.

What processes are involved for a request to access data/document

The request is first submitted to the principal investigator. The data is then sent to the applicant in coordination with other research colleagues and in determining the applicant's purpose.

Comments