Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of extremely low frequency pulsed electromagnetic field and low level laser therapy on acute stroke

Protocol summary

Study aim
We sought to answer the question that the combination of these two methods "extremely low frequency pulsed electromagnetic field and low level laser therapy" could be more effective on acute stroke?

Design
This study was designed as a single-blind randomized clinical trial. According to a computer-generated randomization schema, the eligible 52 patients were randomly assigned into two groups: patients (n=26) and control group (n=26).

Settings and conduct
Stroke patients admitted to Shohahda Hopital Neurology Ward, Tehran, Iran

Participants/Inclusion and exclusion criteria
Not receiving anti thrombolytic therapy; aged over 18 years old; the first stroke; hemisphere; symptoms begin over the last 48 hours; NIHSS> 4 and stable patient with steady clinical awareness and ability to perform simple voice commands.

Intervention groups
EMF-ELF at 1 mT for 5 days per day from 45 minutes and an infrared laser with a wavelength of 840 nm and 12 watts

Main outcome variables
Mini Mental Status Exam NIHSS; Barthel’s index; Geriatric Depression Scale and modified Rankin Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180913041031N1**
Registration date: **2019-05-28, 1398/03/07**
Registration timing: **retrospective**

Last update: **2019-05-28, 1398/03/07**
Update count: **0**

Registration date
2019-05-28, 1398/03/07

Registrant information

Name
Amir Rezaei

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2271 8001

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amir_rezaei@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-27, 1397/04/06

Expected recruitment end date
2018-11-27, 1397/09/06

Actual recruitment start date
2018-06-27, 1397/04/06

Actual recruitment end date
2018-12-27, 1397/10/06

Trial completion date
2018-12-27, 1397/10/06

Scientific title
Efficacy of extremely low frequency pulsed electromagnetic field and low level laser therapy on acute stroke

Public title
Effect of Electromagnetic field and laser on Stroke

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Older than 18 yo First episode of ischemic stroke

Involvement of only one hemisphere Symptoms begins in less than 48 hours ago Conscious Clinically stable Can performe simple verbal commands Signed informed consent form

Exclusion criteria:

Acute ICH Past history of ischemic or hemorrhagic stroke Past history of seizure Particiating in another clinical trial mRS score>1 before trial Lacunar infarct Pregnancy

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization sequence was created using Excel 2016 (Microsoft, Redmond, WA, USA) with a 1:1 allocation using random block sizes of 2 by an independent doctor.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patient put the hat on his head but he/she is not aware that the devise is turned on/off.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commitee of Shadid Behshti University of Medical Sciences

Street address

Next to Taleqani Hospital. , A'rabi St, Yemen St

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-06-26, 1397/04/05

Ethics committee reference number

IR.SBMU. MSP.REC.1397.331

Health conditions studied

1

Description of health condition studied

Acute ischemic stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Laser therapy and Electromagnetic Field can cause significant increase in NIHSS score.

Timepoint

At the beginning of trial and after 45 days

Method of measurement

Questionnaire

2

Description

Laser therapy and Electromagnetic Field can cause significant increase in MMSE score.

Timepoint

At the beginning of trial and after 45 days

Method of measurement

Questionnaire

3

Description

Laser therapy and Electromagnetic Field can cause significant increase in GDS score.

Timepoint

At the beginig of trial and after 45 days

Method of measurement

Questionnaire

4

Description

Laser therapy and Electromagnetic Field can cause significant increase in Barthel 's index score.

Timepoint

At the beginning of trial and after 45 days

Method of measurement

Questionnaire

5

Description

Laser therapy and Electromagnetic Field can cause significant increase in MRS score.

Timepoint

At the beginning of trial and after 45 days

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
EMF_ELF (1mt) for 5 consequtive days up to 45 mins and infrared laser with 840nm (12w)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital
Full name of responsible person
Amir Rezaei
Street address
Shahrdari ST , Tajrish Sq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Next to Taleqani hosp, A'rabi St., Yemen St.
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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
Shahid Beheshti University of Medical 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amir Rezaei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

the whole information can be given to researchers as needed

When the data will become available and for how long

from april 2019

To whom data/document is available

researchers whom working at scientific institute

Under which criteria data/document could be used

if there in no contradiction due to our institute regiulation we are very please to do this matter.

From where data/document is obtainable

Dr. Amir Rezaei Shohada tajrish Hospital, Tehran amir_rezaei@sbmu.ac.ir

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

after consulting with chancellor in research affairs we are very pleased to handle the informatins.

Comments