

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of repetitive transcranial magnetic stimulation on pain control in cancer amputee patients with Phantom Limb Pain

Protocol summary

Study aim

Determine and comparison the pain and depression scores in patients with phantom limb pain before intervention, immediately after each session, one month and six months after treatment with rTMS and compared with control group

Design

Clinical trial with control group, with parallel groups, double blind, randomized

Settings and conduct

The study is conducted in the Physical Medicine and Rehabilitation Department of Firozgar Hospital. The researcher gives the patient a packet containing the type of treatment and the only physician is aware of the patient's placement in the intervention or control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Patients with phantom limb pain after amputation due to cancer • Resistant to treatment with gabapentin or pregabalin dosage after one month • Pass at least three months from the time of amputation
Exclusion criteria: • history of seizure • spastic lesion in the brain • Non-symmetric nerve exam with suspicion of central lesion • Inability to complete the pain questionnaire • vascular stent in the heart arteries or head and neck • metal piece in the body

Intervention groups

The intervention group receives rTMS in the Primary Motor Cortex Left region with 80% of person MEP and 1000 pulses at a frequency of 5 Hz. In the control group uses the simulated rTMS sample without pulse.

Main outcome variables

pain score, depression score

General information

Reason for update

Acronym

RTMS

IRCT registration information

IRCT registration number: **IRCT20180619040148N1**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **prospective**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Masumeh Bagherzadeh Cham

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1612

Email address

bagherzadehcham.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of repetitive transcranial magnetic stimulation on pain control in cancer amputee patients with Phantom Limb Pain

Public title

Evaluation of RTMS on Phantom Limb Pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Amputee Patients with phantom pain due to cancer
 Resistant to treatment with gabapentin or pregabalin
 dosage after one month Pass at least three months from
 the time of amputation
Exclusion criteria:
 history of seizure spastic lesion in the brain Non-
 symmetric nerve exam with suspicion of central lesion
 Inability to complete the pain questionnaire vascular
 stent in the heart arteries or head and neck metal piece
 in the body

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
The researcher provided packages containing treatment
with rTMS or treatment with sham and each patient is
randomly given one of them. The patient gave the
envelope to the therapist and the physician uses rTMS or
sham for the patient's contents in the package. Both
rTMS and sham have the same shape and sound.
Therefore the patient and the researcher do not know
the type of patient's allocation to the test group or the
control group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical
Sciences

Street address

Firozgar Hospital, Beh Afarin St, Karimkhan St, Valiasr
Sq

City

Tehran

Province

Tehran

Postal code

۱۵۹۳۷۴۷۸۱۱

Approval date

2018-03-01, 1396/12/10

Ethics committee reference number

IR.IUMS.REC 1396.32657

Health conditions studied

1

Description of health condition studied

amputee patients with phantom limb pain

ICD-10 code

G54.6

ICD-10 code description

Phantom limb syndrome without pain

Primary outcomes

1

Description

pain score

Timepoint

Measurement of pain score before the intervention,
immediately after each treatment session, one month
and six months after the end of treatment.

Method of measurement

McGill Pain score questioner

Secondary outcomes

1

Description

depression score

Timepoint

Measurement of depression score before the
intervention, immediately after each treatment session,
one month and six months after the end of treatment.

Method of measurement

Beck Depression Inventory-II

Intervention groups

1

Description

Intervention group: Receiving 10 sessions' rTMS in the
Primary Motor Cortex Left area using 80% MEP per
person and 1000 pulses at a frequency of 5 Hz.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar hospital

Full name of responsible person

Gholam Reaz Raissi

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Firozgar Hospital, Beh Afarin St, Karimkhan St, Valiasr Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Masumeh Bagherzadeh Cham

Position

assisstant

Latest degree

Ph.D.

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate

Latest degree

Subspecialist

Other areas of specialty/work

Physical Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available