# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 8214 1612

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**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 shame 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**

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**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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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Iran University of Medical Sciences

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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**
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**Position**
assisstant

**Latest degree**
Ph.D.

**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