Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effect of repetitive transcranial magnetic stimulation in cervical spondylotic myelopathy patients after surgery

Protocol summary

Study aim
Evaluation of the effect of repetitive transcranial magnetic stimulation in cervical spondylotic myelopathy patients after surgery

Design
This study will be performed as a randomized and prospective clinical trial on 56 patients after cervical myelopathy spondylosis.

Settings and conduct
Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria
Inclusion Criteria: All the patients with a diagnosis of cervical spondylotic myelopathy and neurological deficits in the neurological exam. The patients whose information and follow-ups were complete. The patients with an age range between 18 & 70 years old. • The patients with have symptoms between 2 months to 4 years before operation. • The patients in pre-operation cervical spine MRI having one or more levels of stenosis or cord compression. Exclusion Criteria: • The patients with cognitive disorder, neurological or musculoskeletal disorder • The patients with any contraindication for receiving magnetic stimulation like vascular clipping in the brain, intraocular prosthesis and etc.

Intervention groups
28 patients will undergo postoperative rehabilitation with repetitive transcranial magnetic stimulation and physiotherapy (group 1) and 28 patients will undergo postoperative rehabilitation with physiotherapy only (group 2).

Main outcome variables
The neurologic assessment elements (American Spinal Cord Injury Association (ASIA) score, modified Japanese Orthopaedic Association (mJOA) score, Ashworth scale, and Nurick grade) were documented before and after the rehabilitation procedure for each patient.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180604039980N1**
Registration date: **2021-03-13, 1399/12/23**
Registration timing: **prospective**

Last update: **2021-03-13, 1399/12/23**
Update count: **0**

Registration date
2021-03-13, 1399/12/23

Registrant information

Name
Majid Reza Farrokhi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-09, 1400/01/20

Expected recruitment end date
2021-10-12, 1400/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of repetitive transcranial magnetic stimulation in cervical spondylotic myelopathy patients after surgery

Public title
Repetitive transcranial magnetic stimulation and cervical spondylotic myelopathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
• All the patients with a diagnosis of cervical spondylotic myelopathy and neurological deficits in the neurological exam. The patients whose information and follow-ups were complete. The patients with an age range between 18 & 70 years old. • The patients with have symptoms between 2 months to 4 years before operation / Operation to rTMS interval below 6 months. • The patients which in pre operation cervical spine MRI having one or more levels of stenosis or cord compression.
Exclusion criteria:
The patients with cognitive disorder, neurological or musculoskeletal disorder The patients with any contraindication for receiving magnetic stimulation like vascular clipping in the brain, intraocular prosthesis and etc.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
We will perform a prospective single-blind, randomized trial in which 52 cervical myelopathy spondylosis(CSM)patients after surgery will be enrolled. A general practitioner not only will assess 52 patients for eligibility, but also will evaluate baseline characteristics of eligible patients before randomization. Written informed consent will be obtained from all patients before operation. Eligible participants will be randomly assigned to two groups by opening sealed envelopes. The envelopes will be prepared beforehand and sorted randomly by using random allocation software (computerized random number generators). Randomization will be performed by a neurosurgery resident after the inclusion of the patients into the study by the surgeon. The patient will draw one of the two envelopes indicating the combination of repetitive transcranial magnetic stimulation (rTMS) and physiotherapy or only physiotherapy. The patients will be randomly allocated to one of two groups. 26 patients will be rehabilitated by the combination of rTMS and physiotherapy (group 1) and 26 patients will be rehabilitated by physiotherapy alone (group 2).
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analysts and evaluators will be blind in this study, therefore it will be a single-blind study.
Placebo
Not used
Assignment
Parallel
Other design features
In this study, two groups are defined, in the first stage, both groups receive the same intervention, and then in the second stage, only one group receives the second intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Central building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran
City
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Province
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Postal code
71348-14336
Approval date
2017-07-10, 1396/04/19
Ethics committee reference number
IR.SUMS.MED.1396.47

Health conditions studied

1

Description of health condition studied
Effects of the combination of repetitive transcranial magnetic stimulation (rTMS) and physiotherapy as well as physiotherapy alone on motor and sensory improvement were assessed after spinal cord decompression in patients with CSM.
ICD-10 code
M47.12
ICD-10 code description
Other spondylosis with myelopathy, cervical region

Primary outcomes

1

Description
Motor and sensory changes

Timepoint
Before and after the intervention
Method of measurement
Motor and sensory changes (ASIA score)

2

Description
Ability to walking
Timepoint
Before and after the intervention
Method of measurement
Ability to walking (Nurick scale)

3

Description
Muscle tone
Timepoint
Before and after the intervention
Method of measurement
Muscle tone (modified Ashworth scale).

4

Description
Motor and sensory dysfunction
Timepoint
Before and after the intervention
Method of measurement
Motor and sensory dysfunction:(Modified Japanese Orthopaedic Association scoring system)

Secondary outcomes

1

Description
ASIA score(Motor and sensory changes)
Timepoint
Before and after the intervention
Method of measurement
Motor index scoring: It is done by rating zero to 5 muscle strength and giving a score of zero to 5 to each key muscle. Due to the presence of 5 key muscles in each limb, the maximum score of each limb is 25 points (5 × 5) and in a total of four limbs, the maximum score is 100 points. Sensory index scoring: There is a maximum total of 56 points each for light touch and pinprick (sharp/dull discrimination) modalities, for a total of 112 points per side of the body.

2

Description
Nurick scale(Ability to walking)
Timepoint
Before and after the intervention
Method of measurement
Signs or symptoms of root involvement but without evidence of spinal cord disease→ grade=0 Signs of spinal cord disease but no difficulty in walking → grade=1 Slight difficulty in walking which did not prevent full-time employment→ grade=2 Difficulty in walking which prevented full-time employment or the ability todo all housework, but which was not so severe as to require someone else's help to walk → grade=3 Able to walk only with someone else's help or with the aid of a frame → grade=4 Chair bound or bedridden → grade=5

3

Description
Modified Ashworth scale(Muscle tone)
Timepoint
Before and after the intervention
Method of measurement
0: No increase in muscle tone 1: Slight increase in muscle tone, with a catch and release or minimal resistance at the end of the range of motion, when an affected part(s) is moved in flexion or extension 1+: Slight increase in muscle tone, manifested as a catch, followed by minimal resistance through the remainder (less than half) of the range of motion 2: A marked increase in muscle tone throughout most of the range of motion, but affected part(s) are still easily moved 3: Considerable increase in muscle tone, passive movement difficult 4: Affected part(s) rigid in flexion or extension

4

Description
Modified Japanese Orthopaedic Association scoring system(Motor and sensory dysfunction)
Timepoint
Before and after the intervention
Method of measurement
It is an 18-point scale that addresses upper (0-5 points) and lower extremity (0-7 points) motor function, sensation (0-3 points), and sphincter dysfunction (0-3 points). A score of 18 reflects no neurological deficits whereas a lower score indicates a greater degree of disability and functional impairment.

Intervention groups

1

Description
Control group: Intervention group: Performing physiotherapy on patients after cervical myelopathy spondylosis. Conventional physiotherapy for 2 weeks (each week, 5 sessions, and each session, 30 min). The conventional physiotherapy in this study consisted of, massage and strengthening,
Category
Rehabilitation

2

Description
Intervention group: Performing repetitive transcranial magnetic stimulation (rTMS) and physiotherapy on patients after cervical myelopathy spondylosis. Non-invasive magnetic stimulation of the patient's motor cortex will be performed postoperatively (1800 pulses in

90 trials with a frequency of 10 Hz, 90% motor threshold (MT)) for 2 weeks (each week, 5 sessions and each session, 20 min) and conventional physiotherapy 30 min after each session.The conventional physiotherapy in this study consisted of, massage and strengthening,

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Majid Reza Farrokhi
Position
Neurosurgeon, Fellowship of spinal surgery, Director of Shiraz Neurosciences Research Center
Latest degree
Specialist
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is 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
Not applicable
Title and more details about the data/document
physiotherapy with/without rTMS was performed after surgical decompression in CSM patients and the effects of physiotherapy whit/without rTMS on the motor and sensory improvement were evaluated using neurologic assessment elements (ASIA score, mJOA scale, Ashworth scale, and Nurick grade).
When the data will become available and for how long
After the publication of the results.
To whom data/document is available
All readers
Under which criteria data/document could be used
All data of the patients will be available to the corresponding author of this proposal. For any query on the data of the patients in this study, you can contact Shiraz Neuroscience Research Center and pose your request to the corresponding author of this study.
From where data/document is obtainable
Shiraz Neuroscience Research Center
What processes are involved for a request to access data/document
Contact Shiraz Neuroscience Research Center
Comments