Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of True and Sham Thread Embedding Acupuncture on Spasticity in Multiple Sclerosis Patients

Protocol summary

Study aim

Evaluation the effectiveness and comparing of True and Sham Thread Embedding in acupoints on Spasticity in Multiple Sclerosis

Design

A concealed, block randomized, double-blinded, 3rd phase of sham controlled clinical trial with a parallel group design of 38 patients

Settings and conduct

Patients referred to the neurology clinic of Mashhad Qaem Hospital, suffering from MS, according to the inclusion criteria and the approval of the MS fellowship, are referred to the acupuncture clinic of Imam Reza hospital. After signing the informed consent form, first evaluations are performed. In addition to the routine neurological treatment, the participants are placed in two groups and 30 acupoints are intervented. In True Embedding intervention group, after disinfection, 2cm PDO threads are embedded in the acupoints by a 20 gauge needle. In the Sham control group, the needle is inserted in the same points for blinding, but the thread is not embedded in the tissue. To prevent infection, cephalexin and to control pain, cold compress or Ibuprofen are prescribed. After 4 and 12 weeks, the outcomes are evaluated.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Definite diagnosis of MS; EDSS<7; Age>18; Resistant spasticity; Signing informed consent. Non-Inclusion Criteria: Receiving acupuncture in the last 6 months; Relapse or changing maintenance treatment in the last 2 months; Severe chronic systemic disease, cancers and coagulopathy; Sensitivity to Cephalosporins or thread; Pregnancy, Breastfeeding or uncertain contraception

Intervention groups

Intervention group: True Embedding of Polydioxanone Threads in 30 Acupoints. Sham control group: Needling in 30 Acupoints Without inserting Threads

Main outcome variables

Disability, Spasm, Walking quality, Daily life activities, Pain, Fatigue, Sleep, Urinary symptoms, Depression, Anxiety and Quality of life score

General information

Reason for update

Expected recruitment end date and the McDonald's criteria 2024 were updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121228011912N8**
Registration date: **2024-03-22, 1403/01/03**
Registration timing: **prospective**

Last update: **2026-07-13, 1405/04/22**
Update count: **2**

Registration date

2024-03-22, 1403/01/03

Registrant information

Name

Hamidreza Bahrami Taghanaki

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-03, 1403/01/15

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of True and Sham Thread Embedding Acupuncture on Spasticity in Multiple Sclerosis Patients

Public title
Effect of Thread Embedding Acupuncture on Spasticity of M.S
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of MS based on McDonald's 2024 criteria by a neurologist EDSS<7 Moderate to severe spasticity reported by the patient as NRS score≥4 with poor response to usual antispasmodics Willingness to participate in the study and sign informed consent Not taking anticoagulants No history of any coagulopathy No history of acupuncture in the last 6 months No history of relapse phase in the last 2 months No change in maintenance treatments during the last 2 months No history of sensivity to cephalosporins No history of sensivity to each components of the thread No history of incurable chronic systemic diseases and cancers Not being pregnant or breastfeeding and using a safe contraceptive method
Exclusion criteria:
Imbalance to continue cooperation with the study Incidence of sensivity reaction to the embedded thread Incidence of resistant bleeding requires medicinal intervention Incidence of the relapse phase requires receiving a medicinal pulse
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the online site www.sealedenvelope.com, random allocation is done in two groups A (intervention) and group B (control). Block Randomization will be done with block sizes of 4 and 6 for random allocation. The prepared blocks will be placed inside the envelope. One of the envelopes will be randomly selected according to the order of patients' arrival, and patients will be assigned to groups. Allocation concealment is done using sealed opaque envelopes. By one of the team members, random numbers will be prepared and placed inside the envelope. The envelopes will be closed and their contents will not be visible from the outside. First, the purpose of the study is explained to the person with entry requirement critrias. Then, the person signs the informed consent form and one envelope will be taken and opened and patient will be entered into one of the two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the intervention group is True embedding group and the Sham group is designed as a control group, and the participants are thus blinded. The statistical analyst evaluates the information based on group A and B and is blinded to which group is belongs to A or B.
Placebo
Used
Assignment
Parallel
Other design features
The control group in acupuncture studies is called sham. Embedding studies are limited and the use of sham is not common in them. In this study, the sham is designed in such a way that all the embedding steps are performed, but the thread is not placed in the body tissue.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghoreyshi complex, University Ave
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9138813944
Approval date
2024-03-09, 1402/12/19
Ethics committee reference number
IR.MUMS.REC.1402.345

Health conditions studied

1

Description of health condition studied
Multiple sclerosis (M.S)
ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Disability Status Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Expanded Disability Status Scale (EDSS)

2

Description

Spasticity Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Numerical Rating Scale (NRS)

3

Description

Quality of Walking Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Multiple Sclerosis Walking Scale-12 (MSWS-12)

4

Description

Activities of Daily Living (ADL) Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Barthel Index

5

Description

Pain Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

McGill pain questionnaire

Secondary outcomes

1

Description

Fatigue Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Modified Fatigue Impact Scale (MFIS) questionnaire

2

Description

Quality of Sleep score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI-P)

3

Description

Urinary Symptoms Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Actionable Bladder Symptom Screening Tool (ABSST)

4

Description

Depression Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Hospital Anxiety and Depression Scale (HADS) questionnaire

5

Description

Quality of Life Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

EuroQoL Quality of Life questionnaire

6

Description

Intervention Satisfaction Score

Timepoint

Before intervention and 4 and 12 weeks after intervention

Method of measurement

Scoring (1-10) for satisfaction with the treatment outcomes, willingness to repeat the treatment, and recommendation to other patients

Intervention groups

1

Description
Intervention group: True 2cm Polydioxanon Thread Embedding Acupuncture in 30 acupoints (GV14, GV20, CV4, CV12, BL18, BL20, BL23, SP6, SP9, ST36, KI3, GB20, GB34, LI11 , LR3, LI4, BL57) in one session after disinfection
Category
Rehabilitation

2

Description
Control group: Sham group, Needling of 30 acupoints mentioned above without embedded thread in one session
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic, Qaem Hospital
Full name of responsible person
Mohammad Ali Nahyati
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
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Full name of responsible person
Malika Vaez Tehrani
Position
PhD Candidate
Latest degree
Medical doctor
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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