Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of acupuncture and medical treatment on clinical symptoms and electromyography/nerve conduction velocity (EMG/NCV) changes in patients with lumbar disk herniation

Protocol summary

Summary

Objectives: in this study we try to compare the effect of acupuncture and medical treatment on the clinical symptoms and electromyography/nerve conduction velocity (EMG/NCV) changes in patients with lumbar disk herniation referring to Imam Reza Hospital in 2013-2015. Design: In this interventional study, 105 patients with clinical diagnosis of lumbar disc herniation by a rheumatologist are randomly assigned to either the "acupuncture" ,"medical treatment" and " Sham acupuncture" groups (35 each). Setting and conduct: Before study initiation all participants fill a clinical symptoms questionnaire and are accordingly evaluated by electro-diagnostic tests. Patients in the medical treatment group in addition to two Celebrex 100mg tablets divided in morning and night, the Williams flexion exercises are prescribed daily for one month. The acupuncture groups are referred to an acupuncture specialist to receive acupuncture treatment for one month. Participants including major eligibility criteria: over 20 years of age, confirmed lumbar disc herniation, willing to participate. Interventions: Acupuncture treatment is given 3 times, each session 30 minutes for four weeks. Needle insertion points are fixed in all sessions. Main outcome measure variables: three months after the end of treatment, the patients refer to our clinic to refill the questionnaire and to be re-evaluated for clinical symptoms and EMG/NCV changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122911912N2**
Registration date: **2015-12-03, 1394/09/12**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-12-03, 1394/09/12

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of acupuncture and medical treatment on clinical symptoms and electromyography/nerve conduction velocity (EMG/NCV) changes in patients with lumbar disk herniation

Public title
Comparing the effect of acupuncture and medical treatment on subjective symptoms and neuromuscular electrophysiologic changes in patients with lumbar disk herniation
Purpose
Treatment
Inclusion/Exclusion criteria
Major eligibility criteria: over 20 years of age, confirmed lumbar disc herniation, willing to participate. Major exclusion criteria: Polyneuritis or lesions of the cervical radicolopathy; hypothyroidism; multiple myeloma; amyloidosis; inability to perform daily functions individually; previous acupuncture treatment or surgery for low back pain; insulin dependent diabetes; pregnancy or less than 3 month post partum; epilepsy; cardiovascular disease; history of gastrointestinal disease and intolerance for NSAIDS; history of warfarin or heparin consumption or a hemorrhagic disease; having the indications for surgery according to red flags and yellow flags.
Age
From **19 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Deputy of Research, GHoreyshi building, Daneshgah St.,
City
Mashhad
Postal code
91388-13944
Approval date
2013-04-13, 1392/01/24
Ethics committee reference number
IR.MUMS.REC.1392.22

Health conditions studied

1

Description of health condition studied
Lumbar disc herniation
ICD-10 code
M51
ICD-10 code description
Other intervertebral disc disorders

Primary outcomes

1

Description
Electrodiagnostic (EMG/NCV) changes (CMAP, DML, DSL, MNCV)
Timepoint
before and 3 months after the intervention
Method of measurement
repeating the mentioned tests

Secondary outcomes

1

Description
reduced low back pain
Timepoint
before and 3 months afterintervention
Method of measurement
questionnaire

Intervention groups

1

Description
Study group: Acupuncture treatment with 0.25840mm size needles in 20 acupoints , 3 times a week, each session 30 min for one month
Category
Other

2

Description
Control group: 100mg Celebrex tablets, twice daily (morning and night) plus Williams flexion exercise daily for one month
Category
Treatment - Drugs

3

Description
Added at 2016-09-10: acupuncture with 0.25*40 mm size needles on acupoints no effect on treatment , 3 times a week, each session 30 min for one month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
electrodiagnostics clinic and acupuncture clinic of Imam Reza Hospital,
Full name of responsible person
Hosein Hasanabadi
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mina Ramezani
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Ghoreyshi Building, Daneshgah 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
Vice Chancellor for Research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty