

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Assessment of therapeutic effects of Iranian Nava musical dastgah on Sciatica and comparing it with the conventional medical treatment: a randomised control trial

Protocol summary

Study aim

Determining the therapeutic effects of Iranian "Nava" musical dastgah in the treatment of sciatica and comparing its efficacy with the common treatment

Design

Clinical trial with parallel control group, performed on 112 patients, outcome assessment is blind

Settings and conduct

This study is performed as a clinical trial on patients referred to the Neurosurgery Clinic of Hazrat Rasoul Akram Hospital and the Traditional Medicine Health Center affiliated to Iran University of Medical Sciences. In the intervention group, in addition to the usual treatment, patients listen to a five-minute piece of Iranian "Nava" musical dastgah once a day. And in the control group, patients receive only the usual treatment. The duration of this treatment period is ten days.

Participants/Inclusion and exclusion criteria

Diagnosis of sciatica (low back pain spreading to the lower limbs below the knee) based on clinical examination or MRI; less than two weeks after the onset of pain (continuous or intermittent); age: 35 to 65 years old; moderate to severe pain intensity at the start of treatment (VAS greater than or equal to 4); no indication for lumbar spine surgery; no hearing problems; no history of seizures and noise-aggravated brain lesions; fluency in Persian.

Intervention groups

Intervention group: along side receiving standard treatment and care, every night, the recruits in the intervention group listens to a musical piece in "Mirza abdollah" Radif and "Nava" Dastgah for 5 minutes. This piece is performed by Master Aliasghar Bayani using a "Setar" instrument. Control group: the recruits in control group receive standard treatment and care. the standard care includes home rest, warm compression of the pain field, and 500 mg acetaminophen tablet intake (1-4 tabs

per day in relation to the patient's pain).

Main outcome variables

(Visual Analogue Scale) VAS; Roland- Morris disability questionnaire score

General information

Reason for update

This study needs more time than the previous expected time frame due to the COVID_19 outbreaks.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210226050508N1**

Registration date: **2021-05-31, 1400/03/10**

Registration timing: **prospective**

Last update: **2022-01-19, 1400/10/29**

Update count: **1**

Registration date

2021-05-31, 1400/03/10

Registrant information

Name

mona haghghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-08-23, 1401/06/01 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty	
Scientific title Assessment of therapeutic effects of Iranian Nava musical dastgah on Sciatica and comparing it with the conventional medical treatment: a randomised control trial	Randomisation method: stratified randomization; unit of randomization: odds and even; randomization layers: moderate to severe pain severity; randomization tool: first, the recruits are divided into moderate and severe groups according to the pain severity, then in each category, randomization is performed by block method. Quadruple blocks are selected using a random number table and a random list is prepared. Concealment: a sealed envelope is used. The patient number is written on the envelope and inside the A&B group envelope.
Public title Assessment of therapeutic effects of Iranian Nava musical dastgah on Sciatica and comparing it with the conventional medical treatment: a randomised control trial	Blinding (investigator's opinion) Double blinded
Purpose Treatment	Blinding description In this study, those who cared for patients and provided them with lottery bags and music, and those who collected data and analyzers did not know the study groups.
Inclusion/Exclusion criteria Inclusion criteria: Diagnosis of sciatica or radicular low back pain (low back pain spreading to the lower limbs below the knee) based on clinical examination or MRI Less than two weeks after the onset of pain (continuous or intermittent) Age: 35 to 65 years old Moderate to severe pain intensity at the start of treatment (VAS greater than or equal to 4) No indication for lumbar spine surgery No hearing problems No history of seizures and noise-aggravated brain lesions(Reflex Epilepsy) Fluency in Persian Exclusion criteria: Age less than 35 and more than 65 History of previous lumbar spine surgery Symptoms of cauda equina syndrome (numbness and weakness of both legs, anal pain, perineal anesthesia, sphincter paralysis) Existence of low back pain with specific causes such as fractures, cancer, systemic inflammation and rheumatic diseases, infection and severe degenerative changes Symptoms during treatment that the doctor thinks need further investigation and intervention, such as diseases of other organs Pregnancy Causes hearing problems or noise-aggravated brain damage A history of corticosteroid or opioid use in the last six weeks for any reason Patient dissatisfaction	Placebo Not used Assignment Parallel Other design features This is the first clinical study dedicated specifically to the therapeutic effects of the Iranian Nava music Dastgah.
Age From 35 years old to 65 years old Gender Both Phase N/A Groups that have been masked - Care provider - Outcome assessor - Data analyser Sample size Target sample size: 112 Randomization (investigator's opinion) Randomized Randomization description	Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Iran University of Medical Sciences Street address Iran University of Medical Sciences, Hemmat Highway City Tehran Province Tehran Postal code ۱۴۳۹۶۱۴۵۳۵ Approval date 2021-02-13, 1399/11/25 Ethics committee reference number IR.IUMS.REC.1399.1237
	Health conditions studied <u>1</u> Description of health condition studied Low back pain (Sciatica) ICD-10 code M54.30 ICD-10 code description Sciatica, unspecified side

Primary outcomes

1

Description

VAS (Visual Analogue Scale)

Timepoint

At the beginning of the study, the tenth day and the thirtieth day

Method of measurement

Visual Analogue Scale questionnaire

2

Description

Roland- Morris disability questionnaire score

Timepoint

At the beginning of the study, the tenth day and the thirtieth day

Method of measurement

Roland- Morris disability questionnaire

Secondary outcomes

1

Description

Speilberger State – Trait Anxiety Inventory score

Timepoint

At the beginning of the study, the tenth day and the thirtieth day

Method of measurement

Speilberger State – Trait Anxiety Inventory

2

Description

Daily consumption of analgesic medication

Timepoint

At the beginning of the study, the tenth day and the thirtieth day

Method of measurement

Questionnaire

3

Description

Salmannezhad Mizaj Identification Questionnaire score

Timepoint

At the beginning of the study

Method of measurement

Salmannezhad Mizaj Identification Questionnaire in Persian Medicine

Intervention groups

1

Description

Intervention group: along side receiving standard treatment and care, every night, the recruits in the intervention group listens to a musical piece in "Mirza

abdollah" Radif and Iranian "Nava" musical dastgah for 5 minutes. This piece is performed by Master Aliasghar Bayani using a "Setar" instrument.

Category

Treatment - Other

2

Description

Control group: The recruits in control group receive standard treatment and care. the standard care includes home rest, warm compression of the pain field, and 500 mg acetaminophen tablet intake (1-4 tabs per day in relation to the patient's pain).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Hasan Ghandhari

Street address

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2

Recruitment center

Name of recruitment center

Behesht Iranian traditional medicine healthcare centre

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mona Haghighi

Position

Traditional Iranian medicine Assistant

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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Latest degree

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Other areas of specialty/work

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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