Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of soft tissue release of the thoracic on the improvement of pain, disability, and quality of life in patients with failed back surgery syndrome

Protocol summary

Study aim
The effect of soft tissue release of the thoracic on the improvement of pain, disability, and quality of life in patients with failed back surgery syndrome

Design
Clinical trial with control group, with parallel groups, randomized, on 30 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
After matching the entry criteria of the subjects with the research entry criteria, the treatment conditions are fully explained to the patient and if desired, the informed consent form is completed by the subjects. The selected people are placed in two control and control groups randomly. Both groups receive a common physiotherapy treatment, and the control group receives thoracic soft tissue release as much as the patient can tolerate, 90 seconds per repetition and three repetitions for 5 minutes for each side and rolling massage for 10-20 minutes; And the control group receives common physiotherapy. The place of the study is the physiotherapy center located in the comprehensive rehabilitation center and some private centers that cooperate in this field.

Participants/Inclusion and exclusion criteria
People who have problems after surgery due to failed lumbar surgery.

Intervention groups
Failed back surgery syndrome

Main outcome variables
Pain, disability and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230212057390N3**
Registration date: **2023-10-12, 1402/07/20**
Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**
Update count: **0**

Registration date
2023-10-12, 1402/07/20

Registrant information

Name
Majid Shahbazi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3884 6710

Email address
shahbazim2@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-10-21, 1403/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of soft tissue release of the thoracic on the improvement of pain, disability, and quality of life in patients with failed back surgery syndrome

Public title
The effect of soft tissue release of the thoracic on the improvement of pain, in patients with failed back surgery syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
failed back surgery Not using drugs affecting the functioning of the automatic nervous system
Exclusion criteria:
1. Patients with a history of spinal fracture 2. Patients with spine abnormalities 3. Patients with fear of light 4. Patients with dysfunctional autonomic nervous system 5. Patients with skin sensitivity 6. Patients with alcohol addiction 7. Patients with Horner's syndrome
Age
From **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not 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
Department of Physical Therapy, School of Paramedical and Rehabilitation Sciences, University campus, Azadi square, Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948964
Approval date
2023-09-10, 1402/06/19
Ethics committee reference number
IR.MUMS.REC.1402.165

Health conditions studied

1

Description of health condition studied
failed back surgery syndrome
ICD-10 code
S24.6
ICD-10 code description
آسیب به اعصاب سمپاتیک پشت

Primary outcomes

1

Description
pain
Timepoint
At the start of the trial, five days later, ten days later, and one month afterwards.
Method of measurement
Visual analog scale of pain

2

Description
Disability
Timepoint
At the start of the trial, five days later, ten days later, and one month afterwards.
Method of measurement
Oswestry Disability Index

3

Description
Quality of Life
Timepoint
At the start of the trial, five days later, ten days later, and one month afterwards.
Method of measurement
Functional rating index

4

Description
Blood pressure
Timepoint
At the start of the trial, five days later, ten days later, and one month afterwards.
Method of measurement
Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient is lying on the stomach and the hands are turned inward and attached to the patient's trunk, then the therapist is placed near the patient and places the palms of the hands in a crosswise manner on the soft tissue on both sides of the back spine and in opposite directions with equal pressure. The patient's tolerance to two opposite sides performs the release of the soft tissue. The duration of treatment is 90 seconds and three times for each treatment session, and the duration of the treatment is 5 minutes (21-23). To perform skin rolling, the patient lies on his stomach and then the therapist performs the massage technique from the bottom up by rolling the soft tissue between the thumb and other fingers. The duration of the technique is between 10 and 20 minutes (24, 25). In addition to receiving intervention, patients benefit from a current physiotherapy with the following characteristics: TENS: frequency 80Hz, deflection 250 microseconds US: pulse for 5 minutes HP: 15 minutes

Category

Treatment - Other

2

Description

Control group: Control group patients benefit from a current physiotherapy with the following characteristics: TENS: frequency 80Hz, deflection 250 microseconds US: pulse for 5 minutes HP: 15 minutes

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز فیزیوتراپی واقع در مرکز جامع توانبخشی و بعضی از مراکز خصوصی که در این زمینه همکاری می کنند.

Full name of responsible person

مجید شهبازی

Street address

Department of Physical Therapy, School of Paramedical and Rehabilitation Sciences, University campus, Azadi square, Mashhad, Iran.

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Phone

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Email

shahbazim2@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Shahbazi

Street address

Department of Physical Therapy, School of Paramedical and Rehabilitation Sciences, University campus, Azadi square, Mashhad, Iran.

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Province

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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

Mashhad University of Medical Sciences

Full name of responsible person

Majid Shahbazi

Position

استادیار

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Department of Physical Therapy, School of Paramedical and Rehabilitation Sciences, University campus, Azadi square, Mashhad, Iran.

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Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Shahbazi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Majid Shahbazi

Position
استادیار

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
It will be available for researchers working in academic, scientific and industrial institutions

Under which criteria data/document could be used
Those who make a written request and their written request is approved by the university.

From where data/document is obtainable
Refer to the Department of Physiotherapy of Mashhad University of Medical Sciences

What processes are involved for a request to access data/document
A written request will be given to the physiotherapy department and will be given to the requester if it does not comply with the university rules.

Comments