

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the Effectiveness of Epidural Injection and Acupuncture in Patients With Failed Back Surgery Syndrome

Protocol summary

Study aim

Introducing a safe, easy, cost-effective and more effective treatment method to control pain and improve quality of life in patients with FBSS (Failed Back Surgery Syndrome)

Design

Clinical trial with control group, with parallel groups, without blinding, randomized using block method and using closed envelope tool, on 50 patients

Settings and conduct

Patients referred to the clinic of Baqiyatallah Hospital, including 2 groups of acupuncture and epidural injection, in one group ten sessions of acupuncture and in the other group three sessions of epidural corticosteroid injection are performed. Randomized clinical trial without blinding with the control group .

Participants/Inclusion and exclusion criteria

Patients undergoing lumbar spinal cord surgery with a diagnosis of FBSS(Failed Back Surgery Syndrome). Patients with neuropathy, plexopathy, neck radiculopathy, upper motor nerve neuron involvement and bleeding disorders and taking anticoagulants and the presence of systemic or localized fever and infection, sensitivity to epidural drugs, pregnancy and lactation, uncontrolled heart problems and diabetes excluded from the study.

Intervention groups

1. Acupuncture ten sessions every week, two sessions and 30 minutes per session. The treatment is performed by a physical therapist. Depth of needles 1 to 1.5 cm
2. Epidural injection Three sessions of epidural corticosteroid injection once every two weeks
Drugs used: triamcinolone 40 to 80 mg, bupivacaine 5% (3 to 5 cc), serum hypersaline 15 cc, hyaline 1 vial 1500

Main outcome variables

The primary outcome in this study will be pain intensity, which will be assessed using the visual analogue scale. Secondary outcomes are patients' quality of life. Using the SF-36 quality of life questionnaire, the patients' pain

assessment sections before the intervention will be one week, 1 month and three months after the intervention

General information

Reason for update

Acronym

FBSS

IRCT registration information

IRCT registration number: **IRCT20210114050034N1**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **prospective**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

Registration date

2021-02-13, 1399/11/25

Registrant information

Name

Yaser Hariri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 5531

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Epidural Injection and Acupuncture in Patients With Failed Back Surgery Syndrome

Public title
Comparison of the effect of drug injection with acupuncture in patients with a history of lumbar surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have Undergone Lumbar Spinal Surgery
Exclusion criteria:
Patients with neuropathy Patients with bleeding disorders Consumers of anticoagulants Fear of injections and needles Uncontrolled underlying diseases Pregnancy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
This study is a randomized clinical trial using the block method. In this method, the number of people assigned to each group is usually almost equal. In this method, blocks are formed based on the considered variables and within each block, half of the intervention people and half as a control are considered. The main goal of this method is to balance the number of participants in each group. The randomization unit is individual and the patients are randomized using closed envelope tools and the patients are assigned in a ratio of 1: 1. The two groups will be examined in parallel.

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 Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah Hospital, Mulla Sadra Street after Sheikh Baha'i, Vanak Square
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2020-12-16, 1399/09/26
Ethics committee reference number
IR.BMSU.BAQ.REC.1399.044

Health conditions studied

1

Description of health condition studied
Patients who undergo lumbosacral spinal surgery and have been diagnosed with FBSS(Failed Back Surgery Syndrome) for a variety of reasons, including discopathy and stenosis.

ICD-10 code
G95.8

ICD-10 code description
Other specified diseases of spinal cord

Primary outcomes

1

Description
The primary outcome in this study will be pain intensity, which will be assessed using the visual analogue scale

Timepoint
Patients' pain assessment periods before the intervention will be one week, 1 month and three months after the intervention.

Method of measurement
Using the visual analogue scale criterion

Secondary outcomes

1

Description
Secondary consequences will be the quality of life of patients. Quality of life of patients using SF-36 quality of life questionnaire

Timepoint
Will be examined before the intervention and one week, one month and three months after the last intervention.

Method of measurement
Using the SF-36 Quality of Life Questionnaire

Intervention groups

1

Description

Intervention group: Treatment consists of three sessions once every two weeks. Medications: Triamcinolone 40 to 80 mg, bupivacaine 5% (3 to 5 cc), hypersaline serum 15 cc, ampoule of hyaline 1 vial 1500 treatments including injection of the above substances into the epidural space and with APPROCH C-ARM by C-ARM A physician specializes in physical medicine.

Category

Treatment - Drugs

2

Description

Control group: In acupuncture, ten sessions of treatment include two sessions per week and 30 minutes per session. Acupuncture points: UB36,40,57,60 and distance 2 cm lateral to the spinus processing nut S1-L1. Depth of needles 1 to 1.5 cm. After sterilizing the desired points with 96% alcohol, acupuncture is performed with a 25 * 25 needle and after half an hour, the needle is removed and the desired area is cleaned with alcohol. The treatment is performed by a physical medicine specialist.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital Clinic

Full name of responsible person

Yaser Hariri

Street address

Baqiyatallah Hospital, Mulla Sadra Stree after Sheikh Baha'i, Vanak Square

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Email

dr.hariri.y1397@bmsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr.Gholam Hossein Alishiri

Street address

Baqiyatallah University of Medical Sciences, Shahid Nosrati Alley, Sheikh Baha'i St. South, Mulla Sadra St, Vanak Square

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ghalishiri@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Yaser Hariri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Baqiyatallah University of Medical Sciences, Shahid Nosrati Alley, Sheikh Baha'i St.South, Mulla Sadra St, Vanak Square

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Person responsible for scientific inquiries

Contact

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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