Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

dr.hariri.y1397@bmsu.ac.ir

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

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8755 5531

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

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8755 5531

Email
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

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8755 5531

Fax

Email
dr.hariri.y1397@bmsu.ac.ir

Person responsible for scientific 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

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8755 5531

Fax

Email
dr.hariri.y1397@bmsu.ac.ir

Person responsible for updating data

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

City
Tehran

Province
Tehran

Postal code
1435915371

Phone
+98 21 8755 5531

Fax

Email
dr.hariri.y1397@bmsu.ac.ir

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