

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of transforaminal epidural Autologous Conditioned Serum (ACS) and triamcinolone on pain and disability in patients with unilateral lumbar radicular pain

Protocol summary

Study aim

The effects of Autologous Conditioned Serum therapy on unilateral lumbar radicular pain.

Design

Clinical trial with two experimental groups with parallel groups, double-blind, randomized, phase 3 in 64 patients.

Settings and conduct

The study is performed in Akhtar Hospital (Shahid Beheshti University of Medical Sciences). After recording the pain intensity, the patients are randomly divided into intervention and control groups, and after injecting the drug in the desired area, the pain and disability are assessed.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 64 years with low back pain and spread to a lower limb will take part in this study. The exclusion criteria are spinal canal stenosis, previous lumbar surgery, and systemic disease.

Intervention groups

Under fluoroscopic guidance in the prone position, through transforaminal epidural approach, 3 cc lidocaine 1% plus 40 mg triamcinolone will be injected in the experimental group 1 (triamcinolone group) and 4 cc Autologous Conditioned Serum (ACS) will be injected in the experimental group 2 (ACS group).

Main outcome variables

Assessment of pain intensity using the Visual Analogue Scale (VAS); assessment of disability using the Oswestry Disability Index (ODI).

General information

Reason for update

Acronym

Autologous Conditioned Serum (ACS)

IRCT registration information

IRCT registration number: **IRCT20190513043580N1**

Registration date: **2020-08-17, 1399/05/27**

Registration timing: **retrospective**

Last update: **2020-08-17, 1399/05/27**

Update count: **0**

Registration date

2020-08-17, 1399/05/27

Registrant information

Name

Sarah Hojjati

Name of organization / entity

Shiraz Branch, Islamic Azad University

Country

Iran (Islamic Republic of)

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sarah_hojjati@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-22, 1398/04/31

Expected recruitment end date

2020-03-14, 1398/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of transforaminal epidural Autologous Conditioned Serum (ACS) and triamcinolone on pain and

disability in patients with unilateral lumbar radicalular pain

Public title
The Effect of Transforaminal epidural Autologous Conditioned Serum (ACS) in lumbar pain.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Have 6 weeks of moderate to severe low back pain confirmed by magnetic resonance imaging and have no response to conservative treatments.
Exclusion criteria:
Have a spinal canal stenosis Have a systemic bone or joint disease Have systemic inflammatory diseases Previous history of lumbar surgery Concurrent cervical myelopathy Altered coagulation Ongoing infectious disease Have steroid injections over the past 6 months Presence of neurological deficits Need of early surgery Have an acute trauma Pregnancy

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization process will be done by assigning code to patients and putting them in the sealed envelope and randomly selecting them.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patient evaluators, nurses, and outcome analyzers will not be aware of the type of patient groups until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of

Medical Sciences
Street address
Shahid Beheshti university of medical sciences,
Koodakyar str, Velenjak

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2019-07-18, 1398/04/27

Ethics committee reference number

IR.SBMU.REC.1398.034

Health conditions studied

1

Description of health condition studied

low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Intensity of pain

Timepoint

Before intervention , 3 weeks, 3 , and 6 months after intervention.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Experimental group 1: The patient is placed in a prone position in the operating room. Transformaminal epidural space is determined by X-ray (fluoroscopy) and a spinal needle enters the space. After confirmation with contrast material, 40 mg triamcinolone with 3 cc 1% lidocaine (Elixir Pharmaceutical Company, Iran) is injected.

Category

Treatment - Drugs

2

Description

Experimental group 1: The patient is placed in a prone position in the operating room. Transformaminal epidural space is determined by X-ray (fluoroscopy) and a spinal

needle enters the space. After confirmation with contrast material, 4 cc Autologous Conditioned Serum (ACS) (Orthokin , Germany) is injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Seyed Masoud Hashemi

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Akhtar Hospital, Shariati Str

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Salman Vojdani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

Subspecialist

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Person responsible for updating data

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Latest degree

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study protocol, statistical analysis, and consent form will be provided to those interested in the article that will eventually be published.

When the data will become available and for how long

Immediately after printed article.

To whom data/document is available

All researchers will have access to the information provided in the article.

Under which criteria data/document could be used

For use in future research or in the treatment of patients.

From where data/document is obtainable

Dr Masoud Hashemi, Akhtar Hospital, Sharifi Manesh Str, Tehran.

What processes are involved for a request to access data/document

The applier of the data file should send an email to the researcher. The researcher will inform the applier after the consent of other researchers, and this process will take a maximum of 3 weeks.

Comments