Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Phone
+98 71 3621 5680

Email address
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

Street address
Akhtar Hospital, Shariati Str

City
Tehran

Province
Tehran

Postal code
1964714953

Phone
+98 21 2200 1072

Email
siteAkhtar@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zarghi

Street address
Shahid Beheshti of Medical Sciences, Koodakyar str, Velenjak

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 23871

Email
info@sbmu.ac.ir

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

Street address
Shahid Beheshti of Medical Sciences, Koodakyar str, Velenjak

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2243 1920

Email
vojdansalman@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Hashemi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Akhtar Hospital, Sharifi Manesh Str, Elahieh

City
Tehran

Province
Tehran

Postal code
1964714953

Phone
+98 21 2200 1072

Email
Hashemimasoud@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Sarah Hojjati

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

Street address
Islamic Azad University of Shiraz Branch, Sadra Town

City
Shiraz

Province
Fars

Postal code
74731-71987

Phone
009871361919

Email
Sarah_hojjati@yahoo.com

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