

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of 5% dextrose epidural injections in reducing chronic low back pain

Protocol summary

Study aim

Evaluation of effect of 5% dextrose epidural injections in reducing chronic low back pain

Design

Clinical trial with 3 parallel groups, triple blind, randomized, phase 2 on 150 patients, in block randomization method with the size of 4 and 6, Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>).

Settings and conduct

The aim of the study is evaluation of effect of 5% dextrose epidural injections in reducing chronic low back pain in 150 patients of Valiasr hospital in Arak city. In first group (Dextrose) 10 cc of Dextrose 5%, in second group (local anesthesia) 15 cc of Marcaine 0.5% and in third group (compound) 10 cc of Dextrose 5% and 10 cc of Marcaine 0.5% will be injected to epidural space in the patients in 0,7,15,30 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Moderate to severe low back pain (5 or more score in VAS) for at least 6 months Do not response to common treatment Able to seating position Non-inclusion criteria: Progressive weakness Recent bladder or intestinal dysfunction Local infection Unstable psychological disorders Other chronic pains such as pain of upper extremities Anticoagulation state Pregnancy Indication of surgery Underlying disease such as cardiovascular, renal or severe pulmonary disorders

Intervention groups

In first group (Dextrose) 10 cc of Dextrose 5%, in second group (local anesthesia) 15 cc of Marcaine 0.5% and in third group (compound) 10 cc of Dextrose 5% and 10 cc of Marcaine 0.5% will be injected to epidural space in the patients in 0,7,15,30 days.

Main outcome variables

Patients pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049175N5**

Registration date: **2021-03-01, 1399/12/11**

Registration timing: **prospective**

Last update: **2021-03-01, 1399/12/11**

Update count: **0**

Registration date

2021-03-01, 1399/12/11

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

sh.valibak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2022-10-07, 1401/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 5% dextrose epidural injections in reducing chronic low back pain	
Public title	Effect of 5% dextrose epidural injections in reducing chronic low back pain
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Moderate to severe low back pain (5 or more in VAS(Visual Analogue Scale)) for at least 6 months. Able to seating position Do not response to common treatment Patients with 20-75 years old Exclusion criteria: Progressive weakness Recent bladder or intestinal dysfunction Local infection Unstable psychological disorders Other chronic pains such as pain of upper extremities Anticoagulation state Pregnancy Indication of surgery Underlying disease such as cardiovascular, renal or severe pulmonary disorders
Age	From 20 years old to 75 years old
Gender	Both
Phase	2
Groups that have been masked	• Participant • Investigator • Data analyser
Sample size	Target sample size: 150
Randomization (investigator's opinion)	Randomized
Randomization description	Patients will be allocated into three groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (https://www.sealedenvelope.com/). Concealment is also guaranteed due to the use of permuted balanced block randomization method.
Blinding (investigator's opinion)	Triple blinded
Blinding description	Patient blindness: Drugs in 3 groups are similar in shape and feature. Blindness of person who fill the check lists: Drugs will be ordered and injected by anesthesiologists so the person who fill the check lists will unaware about kind of drug inject to each patient. Analyzer blindness: Data of the patients except kind of drug received will be delivered to analyzer.
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics committee of Arak University of Medical Sciences Street address Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Sardasht street City Arak Province Markazi Postal code 3848176341 Approval date 2021-01-31, 1399/11/12 Ethics committee reference number IR.ARAKMU.REC.1399.316
Health conditions studied	1 Description of health condition studied Chronic low back pain ICD-10 code M54.9 ICD-10 code description Dorsalgia, unspecified
Primary outcomes	1 Description Patients pain score Timepoint In recovery (15 minutes after injection), 2,4,12,24 and 48 hours after injections and after last injection every week till one month and then every month for three months. Method of measurement VAS (Visual Analogue Scale)
Secondary outcomes	empty
Intervention groups	1 Description Intervention group:In first group (Dextrose) 10 cc of 5% Dextrose will be injected to epidural space in 0,7,15,30

days.
Category
Treatment - Other

2

Description
Intervention group:In second group (local anesthesia)
15cc of Marcain 0.5% will be injected to epidural space in
0,7,15,30 days.

Category
Treatment - Drugs

3

Description
Intervention group:In third group (combined) 10 cc of
Marcain 0.5% and 10 cc of 5% Dextrose will be injected
to epidural space in 0,7,15,30 days.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Alireza Kamali
Street address
Valiasr square
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Assistance of research and technology of Arak
university of medical science-Dr Alireza Kamali
Street address
Assistance of research and technology, Payambare
azam institution, Arak University of Medical Sciences,
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3848176341
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Ali Nazemi Rafi
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Assistant professor
Latest degree

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Shamim Valibak
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General physician non-faculty
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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