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

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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

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research@arakmu.ac.ir

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

Anesthesiology

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alikamaliir@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Nazemi Rafi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work
Neurosurgery

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Email
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Shamim Valibak

Position
General physician non-faculty

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Email
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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