Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparison of the effect of topical application of piroxicam gel, diclofenac gel and emla on pain relief of angiocatheter insertion in patients

Protocol summary

Study aim
Comparison of the effect of topical application of piroxicam gel, diclofenac gel and emla on pain relief of angiocatheter insertion in patients

Design
A parallel-group, single-blind, randomized clinical trial in 123 patients

Settings and conduct
The number of 123 patients admitted to surgery department of Valiasr Hospital in Arak, provided that they meet the inclusion criteria and do not have the exclusion criteria, after fully explaining the conditions of the study and obtaining informed consent, will be investigated as the target population. After recording basic vital signs (blood pressure and heart rate), patients will be randomly divided into three groups. The data collection tool in this research will be a personal information questionnaire (age, height, history of venipuncture , etc.) and VAS scale to measure the intensity of pain caused by venipuncture. In all patients, venous cannulation will be done from a specific area, which is the veins on the back of the hand. Also, in all patients, an Angiocath with the same number will be used, and all cannulations will be performed by an experienced nurse. After determining the patient group for blinding, the researcher will cover the tube of intervention drugs with paper covers and then apply the drug in the desired position in each group.

Participants/Inclusion and exclusion criteria
Age range from 15 to 65 years؛ ASA class I, II؛ absence of pain for any reason

Intervention groups
First group: Piroxicam (P), 10 mg of piroxicam gel is placed in the target area (veins on the back of the hand) in dimensions of 2 x 4 cm. The second group: diclofenac (D), 100 mg of diclofenac gel is placed in the target area (veins on the back of the hand) in dimensions of 2 x 4 cm. The third group: Emla (E), 1.5 grams of cream is placed in the desired place (veins on the back of the hand) in dimensions of 2 x 4 cm.

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180107038251N8**
Registration date: **2023-06-12, 1402/03/22**
Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**
Update count: **0**

Registration date
2023-06-12, 1402/03/22

Registrant information

Name
Nazanin Amini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3366 1308

Email address
nazaninamini69@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-21, 1402/03/31

Expected recruitment end date
2023-10-22, 1402/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of topical application of piroxicam gel, diclofenac gel and emla on pain relief of angiocatheter insertion in patients

Public title
Effect of topical application of piroxicam gel, diclofenac gel and emla on pain relief
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age range from 15 to 65 years of old ASA I , II Absence of pain for any reason Absence of verbal, mental and visual disability Absence of pregnancy No history of drug abuse Not using painkillers in the last 24 hours Absence of sensitivity to NSAID Absence of sensitivity to local anesthetics Absence of allergy to vitamin A + D ointment
Exclusion criteria:
Lack of patient consent to participate or continue the study Body mass index more than 30 Presence of peripheral vascular disease and Raynaud's syndrome The presence of scleroderma Failure of the researcher in the first attempt at cannulation
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator

Sample size
Target sample size: **123**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomly assign the samples in three groups, we prepare beads of the same gender and the same shape as the number of samples and write the number of the desired group on each one, then we put the beads in a container and ask the research units to take out one of the beads and in this way the samples will be randomly placed in one of the three groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
After determining the patient group for blinding, the researcher will cover the tube of intervention drugs with paper covers and then apply the desired drug in each group.
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
Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street, Arak, Iran
City
Arak
Province
Markazi
Postal code
1234
Approval date
2023-01-08, 1401/10/18
Ethics committee reference number
IR.ARAKMU.REC.1401.300

Health conditions studied

1

Description of health condition studied
intensity of pain
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Intensity of pain
Timepoint
at 0, 5, 10, 15, 30, and 45 minutes after cannulation
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Piroxicam (P), in the amount of 10 mg of piroxicam gel, is placed in the desired place (veins on

the back of the hand) in dimensions of 2 x 4 cm.

Category

Prevention

2

Description

Intervention group:Diclofenac (D), 100 mg of diclofenac gel is placed in the desired place (veins on the back of the hand) in dimensions of 2x4 cm.

Category

Prevention

3

Description

Intervention group:Emla (E), 1.5 grams of cream is placed in the desired place (veins on the back of the hand) in dimensions of 2 x 4 cm.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Hesameddin Modir

Street address

Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street, Arak, Iran

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1234

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modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Davood Hekmatpou

Street address

Deputy of Research and Technology, Arak University of Medical Sciences, Sardasht, Arak, Iran

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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

Nazanin Amini

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Dr Hesameddin Modir

Position

Anesthesiologist

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The total potential data can be shared after unidentifiable people

When the data will become available and for how long
2024

To whom data/document is available
En Researchers working in academia and academia

Under which criteria data/document could be used
I have no conditions

From where data/document is obtainable
Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street Arak, Markazi Province, Iran

What processes are involved for a request to access data/document
Visit to Arak Medical University, Faculty of Paramedicine, Anesthesiology Department, Ms. Amini

Comments