

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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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+98 86 3417 3507

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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

Contact

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Dr Hesameddin Modir

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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