

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effectiveness of topical lidocaine-prilocaine cream in comparison with lidocaine-diclofenac cream in reduction of pain caused by central venous catheter implantation

Protocol summary

Study aim

Determination of the effectiveness of topical lidocaine-prilocaine cream in comparison with lidocaine-diclofenac cream in reduction of pain caused by central venous catheter implantation

Design

Double-blind, randomized parallel-group clinical trial

Settings and conduct

After obtaining the code of ethics from the ethics committee of Isfahan University of Medical Sciences and obtaining written consent from 100 eligible patients, they are divided into two groups of 50 cases using a computer-generated random number table with 4 blocks. In the first group Xyla-P cream and in the second group lidocaine-diclofenac cream are applied. After 45 min CVC is inserted. Patients' pain score during lidocaine injection and CVC placement is determined and recorded based on VAS from 0 to 10. In addition, the physician's satisfaction with the patient's calmness and rate of restlessness is recorded based on a score of 0 (completely dissatisfied) to 10 (completely satisfied).

Participants/Inclusion and exclusion criteria

Inclusion criteria: All alert adult patients admitted to the emergency department of Al-Zahra and Kashani hospitals and requiring CVC insertion. Exclusion criteria: The presence of visual, mental, and verbal disorders - History of drug addiction- Allergic reaction to local anesthetics - Those who are in a life-threatening condition-, History of analgesic use within 24 hours before the procedure

Intervention groups

Intervention group 1: topical lidocaine-prilocaine cream.
Intervention group 2: topical lidocaine-diclofenac cream

Main outcome variables

The severity of pain is measured based on the VAS scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038549N11**

Registration date: **2021-05-18, 1400/02/28**

Registration timing: **retrospective**

Last update: **2021-05-18, 1400/02/28**

Update count: **0**

Registration date

2021-05-18, 1400/02/28

Registrant information

Name

Farhad Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-15, 1398/10/25

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

2020-01-15, 1398/10/25

Actual recruitment end date

2021-04-20, 1400/01/31

Trial completion date

2021-04-20, 1400/01/31

Scientific title

Effectiveness of topical lidocaine-prilocaine cream in comparison with lidocaine-diclofenac cream in reduction of pain caused by central venous catheter implantation

Public title

Evaluation of the effect of lidocaine-diclofenac cream in reducing local pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All adult patients referred to the emergency department of al-Zahra and Kashani hospitals Need for Central Venous Catheter Insertion Alert Stable vital signs

Exclusion criteria:

Visual, mental, or verbal disorders History of favism, methemoglobin, renal and liver disease Skin diseases at or around the CVC insertion site History of drug addiction, History of analgesic use within 24 hours before the procedur

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

After the arrival of the patients to the emergency department, they are divided into 2 groups by a computer-generated random number table with 4 blocks. The selected subjects will be divided into each study group in a randomized block method using 6 rows of four blocks (ABAB-BABA-ABBA-BAAB-AABB-BBAA). Xyla-P group (A) and lidocaine-diclofenac group (B). Then, from the created blocks, enough blocks are randomly selected to reach the required sample size. Select the number of blocks from the table of random numbers and based on these numbers, the sequence of blocks in each group will be determined. All this will be done with software called Sealed Envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Lidocaine-diclofenac cream is prepared by the Faculty of Pharmacy of Isfahan University of Medical Sciences and the same is packed with Xyla-P cream, and then numbered and given to the nurse. The nurse and the physician and the patient do not know the ointment content.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

sfahan University of Medical Science, Hezarjrib Street, Isfahan City

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Province

Isfahan

Postal code

8174673461

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.MUI.MED.REC.1398.063

Health conditions studied**1****Description of health condition studied**

Procedural pain

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The severity of pain

Timepoint

After central venous catheter (CVC) insertion

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

The severity of pain

Timepoint

After lidocaine injection

Method of measurement

2**Description**

Drug side effects such as redness, whitening and skin blemishes

Timepoint

Every 5 minutes until the time of discharge

Method of measurement

Observation

Intervention groups1**Description**

Intervention group: Patients are treated with Xyla-P cream. A 5% Xyla-P cream is a combination of 2.5% lidocaine and 2.5% perlocaine produced by Iranian chemistry company Iran. For each patient, 2 grams of 5*5 cm spam cream are applied and then covered with gas. After 45 min local lidocaine is injected and then CVC is inserted.

Category

Treatment - Drugs

2**Description**

Intervention group: Patients are treated with lidocaine-diclofenac cream. This cream is a combination of 2% lidocaine and 1% diclofenac and is prepared with the Faculty of Pharmacology (Isfahan University of Medical Sciences). . For each patient, 2 grams of 5*5 cm spam cream are applied and then covered with gas. After 45 min local lidocaine is injected and then CVC is inserted.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Alzahra hospital

Full name of responsible person

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2**Recruitment center****Name of recruitment center**

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

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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

Esfahan University of Medical Sciences

Proportion provided by this source

10

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
Esfahan University of Medical Sciences
Full name of responsible person
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Associate professor
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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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All of data after coding

When the data will become available and for how long

Accessibility after 2022

To whom data/document is available

Everyone

Under which criteria data/document could be used

For seemingly studies data released to academic chairman's

From where data/document is obtainable

Isfahan University of Medical Sciences

What processes are involved for a request to access data/document

Emailing to farhad_heidari@med.mui.ac.ir

Comments