

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effectiveness of topical lidocaine-prilocaine cream in comparison with lidocaine-ibuprofen combination cream in reduction of pain during central venous catheterization

Protocol summary

Study aim

Determination of the proper method for creating an appropriate local anesthetic to reduce the pain associated with CVC insertion

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 using random-allocation software package. In the first group Xyla-P cream and in the second group lidocaine-ibuprofen cream are applied. After 45 min CVC is inserted. Patients' pain score during lidocaine injection and CVC placement is determined and recorded based on Visual Analog Score from 0 to 10. In addition, the physician's satisfaction with the patient's calmness and rate of restlessness was 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

En Patients over the age of 18 who are taking topical lidocaine-ibuprofen cream to reduce the pain associated with CVC insertion

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: **IRCT20180129038549N10**

Registration date: **2021-05-12, 1400/02/22**

Registration timing: **prospective**

Last update: **2021-05-12, 1400/02/22**

Update count: **0**

Registration date

2021-05-12, 1400/02/22

Registrant information

Name

Farhad Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3786 8804

Email address

drfarhadheydari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-16, 1400/02/26

Expected recruitment end date

2021-07-17, 1400/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of topical lidocaine-prilocaine cream in comparison with lidocaine-ibuprofen combination cream in reduction of pain during central venous catheterization

Public title

Evaluation of the effect of lidocaine-ibuprofen 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 procedure

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**

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.

Blinding (investigator's opinion)

Double blinded

Blinding description

First, Lidocaine-ibuprofen 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 Science

Street address

Isfahan University of Medical Science, Hezarjrib Street, Isfahan City

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.MUI.MED.REC.1398.703

Health conditions studied

1

Description of health condition studied

Procedural pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

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

Drug side effects such as redness, whitening and skin blemishes

Timepoint

Until the time of discharge

Method of measurement

Standard questionnaire form

2

Description

The severity of pain

Timepoint

After lidocaine injection
Method of measurement
Visual Analogue Scale

Intervention groups

1

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.

Category

Treatment - Drugs

2

Description

Intervention group: Patients are treated with lidocaine-ibuprofen cream. This cream is a combination of 2% lidocaine and 5% ibuprofen 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.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Farhad Heydari

Street address

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2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Farhad Heydari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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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

Six month after publication

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