

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of lidocaine-perilocaine cream with topical ketamine in reducing local pain in patients

Protocol summary

Study aim

Determination of the proper method for creating an appropriate local anesthetic to reduce the pain associated with venipuncture in patients and prevent secondary complications.

Design

Clinical trial with control group, with parallel groups, blind, randomized

Settings and conduct

Emergency department patients are randomly divided into three equal groups. One of the three topical ointments marked with the number is rubbed in place and then the intravenous cannulation is taken to the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All alert adult patients admitted to the emergency department of Al-Zahra and Kashani hospitals and requiring venipuncture. Exclusion criteria: The presence of visual, mental and verbal disorders - Addict in opioids - Sensitization to anesthetic drugs - Those who are in a life-threatening condition

Intervention groups

Patients over the age of 18 who are taking topical ketamine to reduce the pain associated with venipuncture

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: **IRCT20180129038549N2**

Registration date: **2018-02-20, 1396/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-20, 1396/12/01**

Update count: **0**

Registration date

2018-02-20, 1396/12/01

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

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of lidocaine-perilocaine cream with topical ketamine in reducing local pain in patients

Public title

Effect of topical ketamine on pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All adult patients referred to the emergency department

of al-Zahra and Kashani hospitals Need for Peripheral Intravenous Cannulation Alert

Exclusion criteria:
The presence of visual, mental and verbal disorders
Opioids addiction Sensitivity to anesthetic drugs Patients in a life-threatening condition Analgesic drug addict(More than 4 times a week)

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: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly using computer software

Blinding (investigator's opinion)
Double blinded

Blinding description
Ketamine ointment is prepared by a pharmacist and the same is packed with EMLA ointment, and then numbered and given to the nurse. The nurse and the physician and patient do not know the ointment content.

Placebo
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

Sofeh Ave.

City

Isfahan

Province

Isfahan

Postal code

8177777645

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.MUI.REC.1396.3.029

Health conditions studied

1

Description of health condition studied

..

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The severity of pain

Timepoint

After intravenous cannulation

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Time to start anesthetic effect

Timepoint

To an hour of exposure

Method of measurement

Time (minute)

2

Description

Drug side effects such as redness, whitening and skin blemishes

Timepoint

Until the time of discharge

Method of measurement

Observation

Intervention groups

1

Description

Patients are treated with EMLA cream. A 5%EMLA cream is a combination of 2.5% lidocaine and 2.5% perlocaine produced by Iranian chemistry company Iran. For each patient, 2 grams of 4 × 2.5 cm spam cream are applied and then covered with gas.Intervention group:

Category

Treatment - Drugs

2

Description

Intervention group: Patients treated with topical

ketamine (vial 10 ml ketamine hydrochloride 50 mg / ml for i.m / i.v, TRITTAU made in Germany) are treated. To this end, we mixed the injection of 2cc ketamine with 10cc cold cream. Each cc of ketamine contains 50 mg. The solution thus obtained will have a concentration of 10 mg per cubic centimeter. Then, for each patient, we cover a cc of the solution made at the place to be taken and used for gas.

Category

Treatment - Drugs

3**Description**

Control group: placebo

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra and Kashani hospital

Full name of responsible person

Farhad Heydari

Street address

Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd

City

Isfahan

Province

Isfahan

Postal code

8177777645

Phone

+98 31 3620 2020

Email

drfarhadheydari@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Street address

Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd.

City

Isfahan

Province

Isfahan

Postal code

8177777645

Phone

+98 31 3620 2020

Email

drfarhadheydari@gmail.com

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

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

No 7, Aria Building, Sohrevardi Ave.,

City

Isfahan

Province

Isfahan

Postal code

8177777645

Phone

+98 31 3776 9818

Fax**Email**

drfarhadheydari@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Farhad Heydari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

No 7, Aria Building, Sohrevardi Ave.

City

Isfahan
Province
Isfahan
Postal code
8177777645
Phone
+98 31 3776 9818
Fax
Email
drfarhadheydari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Farhad Heydari
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
No7, Aria Building, Sohrevardi Ave.
City
Isfahan

Province
Isfahan
Postal code
8177777645
Phone
+98 31 3776 9818
Fax
Email
drfarhadheydari@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable