Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the effectiveness or ineffectiveness of Valsalva maneuver and EMLA cream on level of venous cannulation pain

Protocol summary

Summary

The present study aims to compare the effect of Valsalva Maneuver and EMLA cream on level of venous cannulation pain. It is a single blind experimental study. 160 patients candidate to general surgeries including ear, nose and throat, ophthalmology and urology bedridden in Department of Internal Medicine, Hazrat Rasul hospital, Javanrud, Kermanshah were selected and randomly divided into 3 experiments groups and a control group. The first experiment group made use of EMLA cream, 30 mlg. After 40 minutes of applying the cream, venous cannulation was accomplished. Valsalva Maneuver was done on the second group through blowing in a plastic pipe connected to a Mercury barometer, and Valsalva Maneuver was accomplished for at least 20 seconds. Venous cannulation was accomplished immediately after that. In the third group, both EMLA cream and Valsalva Maneuver were conducted so that EMLA cream was applied and, after 40 minutes, Venous cannulation was accomplished immediately in conditions similar to the first group. Vaseline was applied to the control group, and Venous cannulation was conducted after 40 minutes. Then, barometer was used to check patients' blood pressure. Heart beat and the percentage of arterial oxygen saturation were checked using Pulse Oximeter. Pain rate was measured 5 minutes before Venous cannulation and immediately after that. Inclusion criteria: avoiding Systemic analgesics; lack of neurologic defects; lack of respiratory, cardiac, glaucoma diseases; no skin allergy or Atopic dermatitis. Exclusion criteria: Intravenous cannula failure in the first attempt.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062814333N37**
Registration date: **2015-07-24, 1394/05/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-24, 1394/05/02

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness or ineffectiveness of Valsalva maneuver and EMLA cream on level of venous cannulation pain

Public title
A Comparative study of the effect of Valsalva maneuver and EMLA cream on level of venous cannulation pain
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria: avoiding Systemic analgesics; lack of neurologic defects; lack of respiratory, cardiac, glaucoma diseases; no skin allergy or Atopic dermatitis. Exclusion criteria: Intravenous cannula failure in the first attempt.
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomized by sealed envelope

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research, Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2015-05-26, 1394/03/05
Ethics committee reference number
Kums.Rec.1394.21

Health conditions studied

1

Description of health condition studied
level of venous cannulation pain
ICD-10 code
Y60.6
ICD-10 code description
During aspiration, puncture and other catheterization

Primary outcomes

1

Description
Pain level
Timepoint
Immediately after catheter insertion
Method of measurement
Using NRS according to criterion score gained from 0 to 10

2

Description
Average venous pressure
Timepoint
5 minutes before venous cannulation and immediately after that
Method of measurement
Using barometer

3

Description
Heart beat
Timepoint
5 minutes before venous cannulation and immediately after that
Method of measurement
Using pulse oximeter

4

Description
Arterial oxygen saturation
Timepoint
5 minutes before venous cannulation and immediately after that
Method of measurement
Using pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description
The first group made use of EMLA cream, made by Astrazeneca,Eczacibasi Ltd, Turkey. Cream surface is covered by a piece of paper and a 2 cc syringe was used

to apply 1 cc, or 2.5 mlg, of the cream on dependent hand where venous cannulation was conducted at 2.5×2.5 cm. after 40 minutes, the dressing was removed from cannulation point and the place was disinfected using cotton drained in alcohol. Then, BP18 IVC was used to do venous cannulation while the patient lay back and his head is against the cannulation point. Also, tourniquet was placed on his forearm.

Category

Treatment - Drugs

2

Description

Valsalva maneuver in the second group was accomplished through blowing in a plastic pipe connected to a mercury barometer (Easylife, china) and holding up mercury bar upper than 20 mmHg for at least 20 seconds. Immediately after that venous cannulation was done similar to the group using EMLA cream.

Category

Treatment - Drugs

3

Description

Both EMLA cream and Valsalva maneuver were applied to the third group. 40 minutes after applying EMLA cream and in similar conditions to the first group, venous cannulation was done immediately after Valsalva maneuver.

Category

Treatment - Drugs

4

Description

All the conditions to the group using EMLA cream were considered to the fourth group. the difference is that Vaseline (Kimiagar-Toos Ltd, Iran) is used in the fourth group instead of EMLA cream. After 40 minutes venous cannulaton was accomplished.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Hospital, Javanrod

Full name of responsible person

Mahdi Babaei

Street address

Hazrat Rasool Hospital, Street of Baradarn Amini, Javanrod

City

Javanrod

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Rostam Jalali

Position

Assistance professor of Nursing Training

Other areas of specialty/work

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School of Nursing & Midwifery, First of Dolatabad Boulvard,Eisar Square

City

Kermanshah

Postal code

Phone

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Fax

Email

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty