

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### 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 cannulation 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

Korosh 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

##### Street address

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

##### City

Kermanshah

##### Postal code

##### Phone

+98 83 3827 9304

##### Fax

##### Email

KS\_jalali@yahoo.com

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| <b>Web page address</b>                                   | <i>empty</i>                                     |
| <b>Person responsible for updating data</b>               | <b>Statistical Analysis Plan</b><br><i>empty</i> |
| <b>Contact</b>                                            | <b>Informed Consent Form</b><br><i>empty</i>     |
| <b>Sharing plan</b>                                       | <b>Clinical Study Report</b><br><i>empty</i>     |
| <b>Deidentified Individual Participant Data Set (IPD)</b> | <b>Analytic Code</b><br><i>empty</i>             |
| <b>Study Protocol</b>                                     | <b>Data Dictionary</b><br><i>empty</i>           |