Comparison of Valsalva maneuver and EMLA ointment in terms of their effectiveness on the pain of vascular needles insertion in hemodialysis patients

Protocol summary

Study aim
This study aimed to compare the effect of Valsalva maneuver and EMLA ointment on the severity of pain caused by fistula cannulation.

Design
Double blind, randomized clinical trial, with control group, with a parallel group design of 75 patients under hemodialysis.

Settings and conduct
This study will be performed in the hemodialysis department of Kowsar Hospital in Semnan. In the first group, 30 mg EMLA ointment is used, and after 60 minutes, the fistula is cannulated. In the second group, to perform the Valsalva maneuver, after blowing into a plastic tube attached to a mercury sphygmomanometer, perform the Valsalva maneuver for at least 20 seconds, and the fistula can be cannulated at the same circumstance as the first group. In the control group, vitamin A + D ointment is used and fistula cannulation is applied after 60 minutes. Patients assignment to three groups will be randomly and blindly.

Participants/Inclusion and exclusion criteria
Inclusion criteria: hemodialysis started at least 3 months ago; no addiction and dependence on painkillers; no pain before cannulation; no use of sedatives in the last 24 hours; no wound in the fistula area; no history of Favism, congenital or idiopathic methemoglobinemia, liver disease, asthma, skin allergies, dermatitis, thrombophlebitis, active gastrointestinal bleeding; lack of treatment with sulfonamide drugs, nitrate and phenobarbital. Exclusion criteria: unsuccessful cannulation in the first step and repeated insertion of the needle into the skin.

Intervention groups
The study will be performed on two groups of interventions, including Valsalva maneuver or EMLA ointment, and one control group, including vitamin A + D ointment.

Main outcome variables
Pain severity due to fistula cannulation

General information

Reason for update

Acronym
IRCT registration information
IRCT registration number: IRCT20120109008665N12
Registration date: 2020-06-13, 1399/03/24
Registration timing: prospective

Last update: 2020-06-13, 1399/03/24
Update count: 0

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-05, 1399/04/15

Expected recruitment end date
2020-11-05, 1399/08/15

Actual recruitment start date
Scientific title
Comparison of Valsalva maneuver and EMLA ointment in terms of their effectiveness on the pain of vascular needles insertion in hemodialysis patients

Public title
Comparative study of Valsalva maneuver and EMLA ointment on pain intensity due to fistula cannulation

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
- Age over 18 years
- History of at least 3 months of hemodialysis
- No addiction or dependence on painkillers
- No pain before cannulation
- Do not use the sedative at the last 24 hours
- Namely, in the fistula area
- No history of skin allergies, or dermatitis
- Not treated with sulfonamides, nitrates and phenobarbital
- Not having a pacemaker
- No history of Alzheimer's disease, dementia, peripheral vascular disease, diabetic neuropathy, liver disease
- Lack of respiratory problems, brain problems, glaucoma, increased intracranial pressure and recent eye surgery

Exclusion criteria:
- Patients who are unable to perform the Valsalva maneuver by holding the mercury column above 20 mm Hg for 20 seconds
- Unsuccessful cannulation in the first step
- Repeated insertion of the needle into the skin
- Patients with known heart attack or those with hemodynamic problems or dangerous arrhythmias

Age
- From 18 years old to 80 years old

Gender
- Both

Phase
- N/A

Groups that have been masked
- Participant
- Outcome assessor
- Data analyser

Sample size
- Target sample size: 75

Randomization (investigator's opinion)
- Randomized

Randomization description
- Patients will be randomly assigned to three groups of A: EMLA ointment, B: Valsalva maneuver, and C: control using 75 sealed envelopes containing the letters A, B, and C equally. Patients will select the envelope themselves.

Blinding (investigator's opinion)
- Double blinded

Blinding description
- Participants are randomly assigned to groups using sealed envelopes containing letters A, B, and C, each identifies the intervention or control groups. The outcome assessor, and the data analyst are unaware of the allocation of individuals to intervention and control groups.

Placebo
- Used

Assignment
- Parallel

Other design features

Secondary Ids
- empty

Ethics committees

1

Ethics committee
- Name of ethics committee
  - Semnan University of Medical Sciences
- Street address
  - Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran
- City
  - Semnan
- Province
  - Semnan
- Postal code
  - 3519899951
- Approval date
  - 2020-06-02, 1399/03/13
- Ethics committee reference number
  - IR.SEMUMS.REC.1399.061

Health conditions studied

1

Description of health condition studied
- Acute pain
- ICD-10 code
  - G89.18
- ICD-10 code description
  - Other acute postprocedural pain

Primary outcomes

1

Description
- The severity of the pain
- Timepoint
  - The first stage without intervention - the second stage after the intervention

Method of measurement
- Visual Analogue Scale

Secondary outcomes
- empty
**Intervention groups**

1

**Description**
Intervention group: 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 hand where fistula cannulation was conducted at 2.5×2.5 cm. after 60 minutes, the dressing was removed from cannulation point and the place was disinfected using cotton drained in alcohol. Then, BP16 IVC was used to do fistula cannulation while the patient lay back and his head is against the cannulation point.

**Category**
Treatment - Drugs

2

**Description**
Intervention group: 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 fistula cannulation was done similar to the group using EMLA cream.

**Category**
Treatment - Drugs

3

**Description**
Control group: All the conditions to the group using EMLA cream were considered to the third group. the difference is that vitamin A+D (Raha Pharma Co, Iran) is used in the third group instead of EMLA cream. After 60 minutes fistula cannulation was accomplished.

**Category**
Placebo

**Recruitment centers**

1

**Recruitment center**
Kowsar hospital affiliated to Semnan University of Medical Sciences

**Full name of responsible person**
Hassan Babamohamadi

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**
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**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**
Semnan University of Medical Sciences

**Proportion provided by this source**
100

**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**
Semnan University of Medical Sciences

**Full name of responsible person**
Hassan Babamohamadi

**Position**
Associate professor

**Latest degree**
Ph.D.
Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available