Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effect of Pain Less Spray and cold compress on reducing pain caused by venipuncture in patients admitted to the emergency room

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
A clinical trial with the control group, with parallel groups, blind randomized

Settings and conduct
After obtaining the code of ethics from the ethics committee of Isfahan University of Medical Sciences and obtaining written consent from 201 eligible patients, they are divided into three groups using a computer-generated random number table with 4 blocks. In the first group painless spray and in the second group cold compress and in third group placebo are applied. After 10 min intravenous cannulation is inserted. Patients' pain score during intravenous cannulation placement is determined and recorded based on NAS from 0 to 10.

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 - Sensory and motor disorders of the upper extremities - Sensitization to anesthetic drugs - Those who are in a life-threatening condition

Intervention groups
Patients over the age of 18 who are taking painless spray to reduce the pain associated with venipuncture

Main outcome variables
The severity of pain is measured based on the NAS scale.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180129038549N13**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**
Update count: **0**

Registration date
2021-12-11, 1400/09/20

Registrant information

Name
Farhad Heydari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-01, 1400/09/10

Expected recruitment end date
2022-04-30, 1401/02/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Pain Less Spray and cold compress on reducing pain caused by venipuncture in

patients admitted to the emergency room

Public title
Evaluation of the effect of painless spray 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:
The presence of visual, mental and verbal disorders Sensitivity to anesthetic drugs Sensory or motor disorder of the upper extremities
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
After the arrival of the patients to the emergency department, they are divided into 3 groups by a computer-generated random number table with 4 blocks.
Blinding (investigator's opinion)
Single blinded
Blinding description
In the group receiving Pain Less Spray, this spray is used ten minutes before venipuncture of the upper limb at the site of venipuncture. In the group receiving a cold compress, ten minutes before the venipuncture, the cold compress is placed at the venipuncture site. Saline spray is also used in the control group. After 10 minutes in all three groups, venipuncture is performed from the back of the hand by one of the three skilled nurses previously identified. All cases of venipuncture are performed with a catheter number 20. The research physician and the nurse who performs the venipuncture do not know which group the patient is in.
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
Isfahan University of Medical Science, Hezarjrib Street, Isfahan City
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2021-10-31, 1400/08/09
Ethics committee reference number
IR.MUI.MED.REC.1400.512

Health conditions studied

1

Description of health condition studied
Procedural pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The severity of pain
Timepoint
After intravenous cannulation
Method of measurement
Numeric Analogue Scale (NAS)

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

Intervention groups

1

Description
Intervention group: A puff of painless spray is used ten minutes before venipuncture of the upper limb at the site

of venipuncture. The intravenous cannulation is inserted in back of the hand by one of the three previously identified skilled nurses.

Category
Treatment - Drugs

2

Description
Intervention group: A cold compress is used ten minutes before venipuncture of the upper limb at the site of venipuncture. The intravenous cannulation is inserted in back of the hand by one of the three previously identified skilled nurses.

Category
Treatment - Drugs

3

Description
Control group: A puff of saline spray is used ten minutes before venipuncture of the upper limb at the site of venipuncture. The intravenous cannulation is inserted in back of the hand by one of the three previously identified skilled nurses.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra hospital

Full name of responsible person
Farhad Heydari

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Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd

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2

Recruitment center

Name of recruitment center
Kashani hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

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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
50

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 the data after coding
When the data will become available and for how long
Six months 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