

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

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

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	Isfahan
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

Street address

Alzahra Hospital, Sofeh Ave., Shahid Keshvari Blvd

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2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

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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