Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study of the Time-Dependent Effectiveness of Topical cold analgesic (Vapocoolant) spray on Venipuncture Pain: Measurements at Two Time Intervals After Application

Protocol summary

Study aim

Evaluating analgesic effect of Vipoculant cooling spray at two intervals (30–60 sec & 5–6 min), effects of gender, age, baseline pain on pain relief, and side effects within first hour.

Design

Randomized, parallel-group, uncontrolled, unblinded trial (n=46). Block randomization (variable block sizes 4 & 6) using randomization.com.

Settings and conduct

This study will be conducted in the emergency department of Imam Khomeini Hospital. Patients requiring venipuncture are identified. After obtaining informed consent and checking inclusion/exclusion criteria, each participant receives a code, and groups are assigned based on randomization blocks and allocation sequence. The venipuncture site is the antecubital fossa. Vipoculant spray is applied from 15 cm for 2 seconds, and the timer starts immediately after application. In the first group, venipuncture is performed 30–60 seconds after spray application; in the second group, 5–6 minutes after. Pain intensity is recorded immediately after the procedure using the NRS. There is no blinding.

Participants/Inclusion and exclusion criteria

Inclusion: 18-65y, GCS=15, informed consent, antecubital IV site. Exclusion: acute/chronic conditions affecting pain, skin lesion at site, drug allergy, neuropathy/chronic pain, analgesics/corticosteroids (4-72h prior), caffeine/nicotine (8h prior), pregnancy/breastfeeding, failed IV access, urgent need (pain>7/10 or unstable vitals).

Intervention groups

Same spray for both groups. Nurse selects/disinfects site. Researcher sprays from 15 cm for 2 sec. Intervention: venipuncture 30–60 sec post-spray. Comparison: 5–6 min post-spray. Pain assessed by NRS.

Main outcome variables

Pain intensity, measured at two time points, 30 to 60 seconds and 5 to 6 minutes after spray application

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260613069778N1**
Registration date: **2026-06-15, 1405/03/25**
Registration timing: **prospective**

Last update: **2026-06-15, 1405/03/25**
Update count: **0**

Registration date

2026-06-15, 1405/03/25

Registrant information

Name

Atousa Akhgar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-22, 1405/04/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study of the Time-Dependent Effectiveness of Topical cold analgesic (Vapocoolant) spray on Venipuncture Pain: Measurements at Two Time Intervals After Application

Public title

Time-Dependent Analgesic Efficacy of Topical Vapocoolant Spray for Venipuncture Pain: A Comparative Study of Two Application Intervals

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

_ Age group 18 to 65 years (excluding children and the elderly due to the possible impact of psychological factors on the perception of pain) _ Having a full level of consciousness (GCS = 15) and the mental and verbal ability to understand instructions and report pain using the NRS scale _ Providing written informed consent to participate in the study. - Patients for whom the antecubital region has been selected by the nurse as the first venipuncture site

Exclusion criteria:

- People with acute or chronic diseases affecting pain perception _ Presence of any active skin disease, injury or abnormality in the area to be tested _ Known history of allergy to chloroethan or other vapocollants_ Known neuropathic diseases or neurological diseases that make the person unable to perceive pain or chronic pain syndromes_ Use of nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids or other analgesics in the 4 to 72 hours before the test_ Use of caffeine or nicotine in the 8 hours before the test_ Pregnancy or breastfeeding.- Failure of antecubital venipuncture by the nurse and selection of another site for venipuncture_ Patients requiring urgent venipuncture and triage level 2 or higher such as having severe underlying pain (pain greater than 7 out of 10) and unstable vital signs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Sequence Generation: The allocation sequence will be generated by a statistician who has no role in the recruitment and intervention process, using the Block Randomization method with variable block sizes of 4 and 6, and with the help of the online software www.randomization.com. Allocation Concealment: The generated allocation sequence will be placed in opaque, serialized envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2026-06-01, 1405/03/11

Ethics committee reference number

IR.TUMS.IKHC.REC.1405.106

Health conditions studied

1

Description of health condition studied

Venipuncture pain in patients requiring peripheral venous catheterization in the emergency department

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain score immediately after venipuncture in the group receiving vapocoolant spray at 30–60 seconds post-application, measured by the Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst possible pain)

Timepoint

Pain score (NRS) is measured at two time points: first, baseline pain is measured before spray application (for both groups). Second, pain is measured immediately after venipuncture, which occurs at 30–60 seconds post-spray for group 1 and at 5–6 minutes post-spray for group 2. Therefore, the primary outcome (venipuncture

pain) is measured at a single time point for each participant, immediately after the procedure, within the allocated interval.

Method of measurement

The measurement tool for the primary outcome is the Numerical Rating Scale (NRS) for pain, which is an eleven-point scale ranging from 0 (no pain) to 10 (worst possible pain). This scale is verbally explained by the outcome assessor to the participant, and the patient's response is recorded as a single integer from 0 to 10.

2

Description

Pain score immediately after venipuncture in the group receiving vapocoolant spray at 5–6 minutes post-application, measured by the Numerical Rating Scale (NRS) from 0 (no pain) to 10 (worst possible pain)

Timepoint

Pain score (NRS) is measured at two time points: first, baseline pain is measured before spray application (for both groups). Second, pain is measured immediately after venipuncture, which occurs at 30–60 seconds post-spray for group 1 and at 5–6 minutes post-spray for group 2. Therefore, the primary outcome (venipuncture pain) is measured at a single time point for each participant, immediately after the procedure, within the allocated interval.

Method of measurement

The measurement tool for the primary outcome is the Numerical Rating Scale (NRS) for pain, which is an eleven-point scale ranging from 0 (no pain) to 10 (worst possible pain). This scale is verbally explained by the outcome assessor to the participant, and the patient's response is recorded as a single integer from 0 to 10.

Secondary outcomes

1

Description

Occurrence of local adverse events including erythema, burning sensation, or allergic reaction at the spray application site

Timepoint

Up to one hour after spray application

Method of measurement

Direct observation by the researcher and verbal report by the participant

2

Description

Successful venipuncture from the same antecubital area where the spray was applied

Timepoint

Immediately after the venipuncture attempt, within the time interval allocated to the group

Method of measurement

Recording the proportion of successful attempts (needle enters the vein without changing site) versus unsuccessful attempts (inability to cannulate from that site)

3

Description

Number of attempts for venipuncture from the sprayed site

Timepoint

During the venipuncture procedure, within the allocated time interval

Method of measurement

Counting the number of needle insertions into the skin (maximum three attempts; needle redirection without complete withdrawal is counted as a new attempt)

4

Description

Overall participant satisfaction with the pain relief method using vapocoolant spray

Timepoint

End of the study, immediately after recording the venipuncture pain score

Method of measurement

Three-point Likert scale including options of "low satisfaction", "moderate satisfaction", and "high satisfaction", asked verbally from the participant

Intervention groups

1

Description

Intervention group: The Vipoculant spray containing chloroethane (brand: Power Deltazex). The venipuncture site in the antecubital fossa will be determined by the collaborating nurse. Prior to administering the spray, the nurse is given the opportunity to select the appropriate venipuncture site and rate the ease of access of this site on a scale of 1 to 5. The venipuncture site will first be disinfected with an alcohol pad, and then the spray will be immediately applied by the intervention officer from a distance of 15 cm for 2 seconds onto the venipuncture site. Venipuncture will be performed within 60 seconds after spray administration, and the pain resulting from venipuncture will be measured and recorded by an evaluator (researcher) using the NRS scale. Venipuncture will be performed by an experienced nurse to reduce the likelihood of first-attempt failure. However, three attempts (needle redirections) are considered a failure. It is expected that within the mentioned time frame, success or failure in venipuncture (as defined above) will occur. If for any reason (e.g., difficult venipuncture) the time of needle insertion exceeds the specified window, that patient will be excluded from the final analysis and replaced with a new patient to maintain group homogeneity.

Category

Treatment - Devices

2

Description
Comparator group: Vipoculant spray containing chloroethane (brand: Power Deltazex). The venipuncture site in the antecubital fossa will be determined by the collaborating nurse. Prior to administering the spray, the nurse is given the opportunity to select the appropriate venipuncture site and rate the ease of access of this site on a scale of 1 to 5. The venipuncture site will first be disinfected with an alcohol pad, and then the spray will be immediately applied by the intervention officer from a distance of 15 cm for 2 seconds onto the venipuncture site. Venipuncture will be performed 5 to 6 minutes after spray administration, and the pain resulting from venipuncture will be measured and recorded by an evaluator using the NRS scale. Venipuncture will be performed by an experienced nurse to reduce the likelihood of first-attempt failure. However, three attempts (needle redirections) are considered a failure. It is expected that within the aforementioned time frame, success or failure in venipuncture (as defined above) will occur. If for any reason (e.g., difficult venipuncture) the time of needle insertion exceeds the specified window, that patient will be excluded from the final analysis and replaced with a new patient to maintain group homogeneity.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Sara Mehri

Street address
Imam Khomeini Hospital., Keshavarz Blvd.

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Email
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Atousa Akhgar

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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Unique title of the shared data document: "Individual participant data from the clinical trial on time-dependent effectiveness of vapocoolant spray on venipuncture pain" After publication of the main results, all fully de-identified individual participant data (coded with no personally identifiable information such as name, surname, or phone number) will be available for sharing with other researchers. These data include demographic information (age, sex), medical history, analgesic use history, baseline pain score, post-venipuncture pain score (primary outcome), adverse events, number of venipuncture attempts, venipuncture success, and patient satisfaction (all primary and secondary outcomes). A data dictionary (variable guide) will accompany the dataset. Access will be granted upon reasonable request to the corresponding author (Dr. Atousa Akhgar) after signing a Data Use Agreement.
When the data will become available and for how long
The data sharing period will commence six months after the publication of the primary results of the study in a peer-reviewed scientific journal. This interval is intended to ensure completion of all planned analyses and fair use of the data by the primary research team. De-identified individual participant data will remain available to qualified researchers for up to five years following the publication date.
To whom data/document is available
Eligible requestors include researchers affiliated with academic institutions, hospitals, and scientific research centers (both public and private). Researchers working in the pharmaceutical or medical device industry may also request access, provided their request is accompanied by a valid research question approved by an independent ethics committee. In all cases, the applicant must submit a clear research proposal and sign a Data Use Agreement ensuring that data will be used only for the approved purpose and that no attempts will be made to re-identify participants. Access for purely commercial purposes (without a documented research question) is not permitted.
Under which criteria data/document could be used
Access to de-identified individual participant data requires submission of an IRB-approved research proposal. Data may only be used for approved, non-commercial analyses. Any attempt to re-identify participants is strictly forbidden. Publications must cite the original source. Data access is granted for a maximum of 12 months, after which all copies must be deleted. Applicants must comply with applicable data protection laws, sign a Data Use Agreement, and provide a final report of findings to the primary research team.
From where data/document is obtainable
Access will be granted upon reasonable request to the corresponding author (Dr. Atousa Akhgar) via email after signing a Data Use Agreement.
What processes are involved for a request to access data/document

Access will be granted upon reasonable request to the corresponding author (Dr. Atousa Akhgar) via email after signing a Data Use Agreement.

Comments