

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of cold spray on venopuncture pain in hemodialysis patients

Protocol summary

Study aim

Determination of The effect of cold spray on venopuncture pain in hemodialysis patients .

Design

double blind, randomized Clinical trials

Settings and conduct

This study will be performed as a randomized clinical trial in 80 hemodialysis patients.,thirty seconds before the cannulation In the intervention group 2 puff of cold spray(Cramer brand) and in the control group 2 puff of distilled water will be sprayed.Then the severity of pain immediately after canulation is assessed by the visual analog scale of pain (VAS) . Data will then be analyzed using SPSS software version 18 .

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Hemodialysis patients with AV fistula or graft access who are more than 18 year and Signed informed consent Exclusion Criteria: . Sensitivity to alcoholic solutions; . Pregnancy; . Use of analgesics within 24 hours before cannulation; . Patient with mental problems and inability to complete the questionnaire and collaboration; Patients with unstable hemodynamics, .participation in another study. Skin lesion at the site of punctuation, . numbness of the limb with vascular access.

Intervention groups

The effect of cold spray on venopuncture pain in hemodialysis patients

Main outcome variables

pain intensify

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038262N1**

Registration date: **2018-07-01, 1397/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-01, 1397/04/10**

Update count: **0**

Registration date

2018-07-01, 1397/04/10

Registrant information

Name

Zahra Shafii

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2315 2013

Email address

shafii_zahra@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cold spray on venopuncture pain in hemodialysis patients

Public title

The effect of cold spray on reducing venopuncture pain in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodialysis patients with AV fistula or graft access age

more than 18 year
Exclusion criteria:
unwillingness of patient to participate in study
hypersensitivity to alcoholic components and solutions
Pregnancy Use of analgesics within 24 hours before
cannulation Patient with mental problems and inability to
complete the questionnaire and unable to collaborate
Patients with unstable hemodynamics participation in
another study Skin lesion at the site of punctuation
numbness of the limb with vascular access

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly assigned to one of the two intervention and comparison groups using the Random allocation Version 1.2 software. In the intervention group, cold spray and in the comparison group, distilled water will be used , and the nurse and patient are not aware of spray type. allocation Concealment is done by using central randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In our study patients,health care providers and investigator will be blinded

Placebo

Used

Assignment

Parallel

Other design features

none

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Rajaei Cardiovascular Research and Treatment Center

Street address

Shahid Rajaei Cardiovascular Research and Treatment Center

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

RHC.AC.IR.REC.1396.43

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

venopuncture pain

Timepoint

at time of intervention

Method of measurement

VAS pain evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Two puff of cold spray will be sprayed on the site of cannulation and after 30 second cannulation will be done

Category

Treatment - Other

2

Description

Control group: Two puff of distilled water will be sprayed on the site of cannulation and after 30 second cannulation will be done

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Rajaei Cardiology Training Center

Full name of responsible person

Zahra Shafii

Street address

Shaheed Rajaei Cardiovascular Medical and Research
Center Valiasr Ave Niayesh Intersection Tehran Iran

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2

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Nashmin Abdi Bastami

Street address

Emam Hossein Hosp. - Madani St. - Tehran - Iran

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davoodihedayat@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shaheed Rajaei Cardiovascular Medical And Research
Center

Full name of responsible person

Zahra Shafii

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Shaheed Rajaei Cardiovascular Medical and Research
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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

Shaheed Rajaei Cardiovascular Medical And Research
Center

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

Shaheed Rajaei Cardiovascular Medical and Research
Center

Full name of responsible person

Zahra Shafii

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

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

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

I have not decided yet - its release plan is still unclear

When the data will become available and for how long

I have not decided yet - its release plan is still unclear

To whom data/document is available

I have not decided yet - its release plan is still unclear

Under which criteria data/document could be used

I have not decided yet - its release plan is still unclear

From where data/document is obtainable

I have not decided yet - its release plan is still unclear

What processes are involved for a request to access data/document

I have not decided yet - its release plan is still unclear

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shaheed Rajaei Cardiovascular Medical And Research Center

Full name of responsible person

Zahra Shafii

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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