Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2026

Comparison of Damask Rose and lidocaine spray on arteriovenous fistula cannulation pain in patients in the hemodialyse ward

Protocol summary

Study aim
Comparison of Damask Rose and lidocaine spray on fistula cannulation pain in the hemodialysis patient

Design
A randomised trial with two groups of intervention and a control group, community-based and pragmatic, with parallel groups

Settings and conduct
This study will be done on hemodialysis patients in hemodialyse ward in Imam Hossein hospital of Malayer. Participants will be randomly divided into three groups and before the cannulation, in the intervention group 1 damask Rose and in group 2 Lidocaine spray will be used. There will be no intervention in the control group. And In all three groups, the severity of pain associated with cannulation will be investigated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with the end-stage renal disease, Use fistula to perform hemodialysis. Exclusion criteria: Sensitivity to topical anesthetic and herbal allergens, Dependence on analgesics drugs

Intervention groups
Intervention group 1: in the first session dialysis procedure and without any interference cannulation performed. At the second session for 5 minutes before the cannulation, the Damask Rose %10 is inhaled. Intervention group 2: The first session is like Group1. at the second session, 5 minutes before cannulation two puffs of spray lidocaine sprayed on the skin surface location. Control group: Both sessions are performed without any intervention.

Main outcome variables
the pain of fistula cannulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180115038377N2**
Registration date: **2018-06-27, 1397/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-27, 1397/04/06**
Update count: **0**

Registration date
2018-06-27, 1397/04/06

Registrant information

Name
shadi asgari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3222 6958

Email address
sh.asgari@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-10, 1397/03/20

Expected recruitment end date
2018-07-11, 1397/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Damask Rose and lidocaine spray on arteriovenous fistula cannulation pain in patients in the hemodialyse ward

Public title

Comparison of Damask Rose and lidocaine spray on arteriovenous fistula cannulation pain in patients in the hemodialyse ward

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Renal failure requires hemodialysis

Exclusion criteria:

Initiation of hemodialysis less than 3 months ago verbal, mental and vision problems History of mental illness Addiction Dependence on analgesic medicines Sensitization to local anesthetics and herbal allergens The ability to smell Nasal fracture nose surgery Severe cold

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The classification blocking method will be used.In this way, patients will be classified according to age, gender, education level and duration of use of the fistula.And in each class, according to the random number table and the six-tier blocks, they are assigned to three groups.

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 Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Facing the Mardom Park, Hamedan Town

City

Hamedan

Province

Hamadan

Postal code

6571915457

Approval date

2018-05-14, 1397/02/24

Ethics committee reference number

IR.UMSHA.REC.1397.093

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

the pain of fistula cannulation

Timepoint

Immediately after the first session without intervention and immediately after the second session with intervention

Method of measurement

visual pain scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In the first session dialysis procedure and without any interference cannulation performed. At the second session, three drops of 10%Damask Rose on a cotton ball and the volunteer should be inhaled from the interval of 7 to 10 cm for a period of five minutes.

Category

Treatment - Drugs

2

Description

Second intervention group: In the first session dialysis procedure and without any interference cannulation performed. At the second session, 5 minutes before the cannulation, two puff of Lidocaine spray are sprayed 5 cm away from the surface of the target area.

Category

Treatment - Drugs

3

Description

Control group: Both sessions are performed routinely, without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital in Malayer

Full name of responsible person

Shadi Asgari

Street address

Shahid Mirzayi Alley, Shohada Ave, Malayer town

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umsha.asgari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

Street address

Hamedan University of Medical Sciences, Facing the Mardom Park, Hamedan Town

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6517838736

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s_bashirian@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Shadi Asgari

Position

Nursing instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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
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