Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of rope ladder and regional cannulation methods on severity and fear of pain of patients undergoing hemodialysis

Protocol summary

Study aim
Comparison of rope ladders and regional cannulation methods on severity and fear of pain of patients undergoing hemodialysis

Design
Two-group parallel clinical trial with 70 patients

Settings and conduct
This two-group clinical trial that will be performed with the participation of 70 patients undergoing hemodialysis in Hamadan in 1400.In group A(rope ladder), Using a 16G needle at an angle of 20 to 45 degrees, at least 5 cm away from the anastomosis area, insert the arterial needle and insert the venous needle at a distance of at least 5 cm from the arterial needle into the appropriate vein. In the second session, the needle entry point is 0.5 to 1 cm away from the arterial and venous needles and cannulation is performed in the previous method for up to six sessions. In the group B(regional) of cannulation in the second to sixth time, the arterial and venous needle is fixed near the site of the first cannulation in the fistula area.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having a venous arterial fistula suitable for regional cannulation and rope ladder, Age between 18 and 65 years, Have a history of at least 3 months of fistula hemodialysis Exclusion criteria: Reluctance of the patient to continue attending the study, Kidney transplantation

Intervention groups
Intervention group A:The researcher uses the rope ladder convolution method for two weeks. Arterial cannulation and venous cannulation are performed three times a week, which are measured each time before and immediately after cannulation in patients with fear of pain and pain intensity. Intervention group B: In this group, the researcher uses the regional cannulation method for two weeks. Arterial and venous cannulation is performed three times a week. Patients' fear of pain and pain intensity are measured each time before and immediately after cannulation.

Main outcome variables
pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160110025929N37**
Registration date: **2021-11-15, 1400/08/24**
Registration timing: **prospective**

Last update: **2021-11-15, 1400/08/24**
Update count: **0**

Registration date
2021-11-15, 1400/08/24

Registrant information

Name
Mehdi Molavi Vardanjani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3422 5056

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of rope ladder and regional cannulation methods on severity and fear of pain of patients undergoing hemodialysis

Public title

Comparison of rope ladder and regional cannulation methods on severity and fear of pain

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Having a venous arterial fistula suitable for regional cannulation and rope ladder Age between 18 and 65 years Have a history of at least 3 months of fistula hemodialysis

Exclusion criteria:

Reluctance of the patient to continue attending the study Kidney transplantation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2021-09-25, 1400/07/03

Ethics committee reference number

IR.UMSHA.REC.1400.498

Health conditions studied

1

Description of health condition studied

chronic kidney disease

ICD-10 code

I13.2

ICD-10 code description

Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease

Primary outcomes

1

Description

Intensity of pain

Timepoint

Immediately after the intervention

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: In this group(rope ladder),using a 16G needle at an angle of 20 to 45 degrees, at least 5 cm away from the anastomosis area and insert the arterial needle and insert the venous needle (16G) at a distance of at least 5 cm from the arterial needle into the appropriate vein. Immediately after cannulation, the pain intensity is measured and in the second hemodialysis session, using a ruler, 0.5 to 1 cm away from both the arterial needle and the venous needle using the ruler in the first session, and the cannulation is performed as before. The same process will be repeated in the third session. And in the second week of cannulation, the fourth session returns to the needle position of the first session, and also the fifth session to the second needle position and the sixth session to the third needle position until the cannulation is done six times.

Category

N/A

2

Description
Intervention group B: In this group(regional) Using a 16G needle with an angle of 20 to 45 degrees with a distance of at least 5 cm from the arterial needle anastomosis and a venous needle (16 G), a distance of five to eight cm is placed from the arterial needle and immediately after cannulation by providing The ruler is measured to the patient, which is scaled from zero to ten, the severity of the pain is measured and then the arterial and venous needle is fixed near the site of the first cannula in the fistula area.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Beesat hospital

Full name of responsible person
Seyed Reza Borzou

Street address
Shahid Beheshti Blvd., Besat hospital, Hamadan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Saeed Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Deputy of research and technology

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
Seyed Reza Borzou

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Seyed Reza Borzou

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Student

Latest degree
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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