

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)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

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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borzou@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

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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

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

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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
Hamedan University of Medical Sciences
Full name of responsible person
Paria Moradi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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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