Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of fistula cannulation in scarred and non-scarred areas on pain intensity and bleeding in hemodialysis patients

Protocol summary

Study aim
Determining the effect of fistula cannulation in two scarred and non-scarred areas on pain intensity and bleeding in hemodialysis patients

Design
Clinical trial one group with crossover, 74 patients. Randomisation was carried out by random allocation software.

Settings and conduct
Patients from 4 selected hospitals of Yazd province, including Emma Jafar Sadegh hospital of Meybod city, Ziaei of Ardakan city, Shahid Rahnemoun and Shohadae_Kargar of Yazd city enter in the study. Intra-fistula cannulation will be performed once at the scar site and again at the non-scar site in the patients. The amount of pain as well as the amount of bleeding after removal of the needle from the fistula at the end of hemodialysis will be measured in each patient in both methods.

Participants/Inclusion and exclusion criteria
At least 3 months of history of hemodialysis through fistula; Be vigilant; Age over 18 years; No difficulty in accessing arteries; Lack of neuropathic disorders; Patients with peripheral vascular injuries

Intervention groups
The intervention is cross-sectional and the cannulation is done once at the scar site and the next time at the non-scar stage, and the amount of pain and bleeding will be assessed.

Main outcome variables
Mean score of pain due to cannulation; mean amount of bleeding due to cannulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210725051986N1**
Registration date: **2021-11-03, 1400/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-03, 1400/08/12**
Update count: **0**

Registration date
2021-11-03, 1400/08/12

Registrant information

Name
Taybeh Dehghani Firoozabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3233 0647

Email address
tay.dehghani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-23, 1400/08/01

Expected recruitment end date
2021-11-21, 1400/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of fistula cannulation in scarred and non-scarred areas on pain intensity and bleeding in hemodialysis patients

Public title
Effect of cannulation in scarred and non-scarred areas on

pain intensity and bleeding in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least 3 months of history of hemodialysis through fistula Alertness Age over 18 years No difficulty in accessing blood vessels Lack of neuropathy and patients with peripheral vascular injuries

Exclusion criteria:

Malignancy and severe infection Patients with skin diseases in or around the fistula Patients who need surgery due to fistula dysfunction

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

More than 1 sample in each individual

Number of samples in each individual: **2**

For each sample, the needle is inserted once into the scar site and once into the non-scar site.

Randomization (investigator's opinion)

Randomized

Randomization description

The available sample (74 patients) is selected based on the inclusion criteria and after extracting the patients' names and referring to the project statistical consultant, they are assigned a three-digit code 001 to 074. Using Random allocation statistical software by simple randomization method and sequence 001 to 074 in a row, the samples are divided into two groups A and B. In group A, first cannulation is performed at the scar site and in group B, first non-scar cannulation is performed and in the next stage, the interventions are shifted.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Shahid Sadoughi University of Medical Sciences

Street address

Central Administration, Bahonar Sq., Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.SSU.REC.1399.157

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.0

ICD-10 code description

Preparatory care for renal dialysis

Primary outcomes

1

Description

The average pain score on the visual analogue scale

Timepoint

After insertion of the needle into the fistula in both methods studied

Method of measurement

Visual Analogue Scale

2

Description

The amount of bleeding after the needle is removed from the fistula

Timepoint

After removal of the needle from the fistula in both methods studied

Method of measurement

Standard Future model scales with a sensitivity of 0.01 g

Secondary outcomes

1

Description

Patient preference for using the cannulation method

Timepoint

After interventions

Method of measurement

űestionnaire

Intervention groups

1

Description
Intervention group: 74 patients are cross-selected for intervention based on inclusion criteria. After extracting, the patients' names were coded and they were placed in one of the two study groups using random allocation software. Intravenous arterial needle No. 20 hemodialysis made by the company Medwayteb and is placed in the fistula at least from a distance of 5 cm from the fistula with an angle of 30 to 40 degrees while the diagonal part of the needle is high. This is done in the first session according to the random allocation to determine the priority in terms of placement in the scar or non-scar fistula and in the next session vice versa for each patient.

Category
Other

2

Description
Control group: The same interventions of the intervention group are performed.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Jafar Sadegh Hospital
Full name of responsible person
Tayebeh Dehghani Firouzabadi
Street address
Janbaz Sq., Basij Blvd.
City
Meybod
Province
Yazd
Postal code
8961977138
Phone
+98 35 3235 1200
Fax
+98 35 3235 1206
Email
Meybodhospital@gmail.com

2

Recruitment center
Name of recruitment center
Zeyaei Hospital
Full name of responsible person
Tayebeh Dehghani Firouzabadi
Street address
Azadi Squ., Moallem Blvd.
City
Ardakan
Province
Yazd
Postal code
895185993
Phone
+98 35 3152 2114
Email
ziaee_hospital@ssu.ac.ir

3

Recruitment center
Name of recruitment center
Shahid Rahnemoun Hospital
Full name of responsible person
Jamileh Delshad
Street address
Farrokhi st., Shahid Beheshti Sq.
City
Yazd
Province
Yazd
Postal code
8913814396
Phone
+98 35 3626 0001
Email
rahnamoon@ssu.ac.ir

4

Recruitment center
Name of recruitment center
Shohadaye Kargar Hospital
Full name of responsible person
Yousef Kargar
Street address
Namaz Sq., Modarres Blvd.
City
Yazd
Province
Yazd
Postal code
0000000000
Phone
+98 35 3182 2000
Email
shohadakargar.hos@tamin.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mostafa Javadi
Street address
opposite the Infertility Center in the summer, BouAli Street, Safaiei Blvd.
City
Yazd

Province
Yazd
Postal code
00000000000
Phone
+98 35 3824 1751
Email
parastari@med.ssu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Taybeh Dehghani firoozabadi
Position
Master student of intensive care nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Shahid Naser Zarei Aly., Shahid Mirbagheri Str.
City
Meybod
Province
Yazd
Postal code
8961817955
Phone
+98 35 3824 1751
Email
Tay.dehghani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mostafa Javadi
Position
Phd of Nursing
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Sadoughi School of Nursing and Midwifery, in front of Infertility Center, Safaieh St., Bouali Blvd.
City
Yazd
Province
Yazd
Postal code
8916877443
Phone
+98 35 3824 1751
Email
javadinurse@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Taybeh Dehghani Firoozabadi
Position
Master student of intensive care nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
in front of Infertility Center, Safaieh St., Bouali Blv.
City
Yazd
Province
Yazd
Postal code
0000000000
Phone
+98 35 3824 1751
Email
Tay.Dehghani@gmail.com

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document

Information will be published without the names of participants and hospitals. Confidentiality of personal information will be assured

When the data will become available and for how long

After the publication of the results and the final defense of the dissertation

To whom data/document is available

Supervisor, members of the faculty / university research committee

Under which criteria data/document could be used

Improving patient conditions and use for evidence-based care

From where data/document is obtainable

Dr. Mostafa Javadi

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

Written request from the researcher or scientific organizations and the university

Comments