Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Comparative study of the effect of using silver nanoparticles dressings and alcoholic chlorhexidine impregnated dressings and conventional dressings on the rate of infection of temporary hemodialysis catheters in hemodialysis patients

Protocol summary

Study aim

Determining the effect and comparison of the use of nanosilver dressings and alcoholic chlorhexidine impregnated dressings and conventional dressings on the infection rate of temporary hemodialysis catheters in patients referred to the Educational-therapeutic hemodialysis centers of Urmia in 2021-2022

Design

The clinical trial consists of a control group with randomized parallel groups without blinding, which will be performed on a total of 120 people in three groups of 40 people and the results of the interventions will be analyzed with SPSS 16

Settings and conduct

The sample size for the above study is 120 hemodialysis patients with a temporary catheter with a negative skin culture test. Our study has three groups of control (common dressing) (n=40), dressing with alcoholic chlorhexidine (n=40) and nanosilver dressing (n=40). 120 patients will be selected according to the inclusion criteria and skin culture will be obtained and covered with the desired dressing. After determining the answer of skin culture, patients with negative culture will be retained and will be dressed two more times and people with positive skin culture will be dressed. They will be removed from the study and replaced with another negative skin culture. Up to 120 people to be completed in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with renal insufficiency with temporary temporal and subclavian catheters Exclusion criteria: Existence of infectious disease

Intervention groups

In one group, a nanosilver dressing will be used for the hemodialysis catheter place. In the other group, an alcoholic chlorhexidine will be used for the dressing, and in the third group, the usual dressing, (povidone iodine), will be used.

Main outcome variables

Evaluation of temporary catheter infection rate in three dressing methods

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210412050938N1**
Registration date: **2021-06-28, 1400/04/07**
Registration timing: **retrospective**

Last update: **2021-06-28, 1400/04/07**
Update count: **0**

Registration date

2021-06-28, 1400/04/07

Registrant information

Name
Omid Pourmehr
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date
2021-06-20, 1400/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of using silver nanoparticles dressings and alcoholic chlorhexidine impregnated dressings and conventional dressings on the rate of infection of temporary hemodialysis catheters in hemodialysis patients

Public title
the effect of dressing on the infection rate of hemodialysis catheters in hemodialysis patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in research Patients with renal insufficiency with temporary temporal and subclavian catheters Patients with negative skin culture No respiratory, pulmonary and blood infectious diseases (file review) Patients who do not receive intravenous or oral antibiotics Patients who do not take immunosuppressive drugs
Exclusion criteria:
Reluctance to continue the research process
Age
From **35 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into three groups using a simple randomization method based on a table of random numbers. According to the sample size (120 patients), patients will first be given a code from 1 to 120 (given that the number of patients is three digits). Therefore, the given codes will be three digits: 001, 002, ..., 120) Then a number will be randomly selected from the table and we will go from top to bottom in a column in the table until the sample size is examined. To be completed. In this case, patients between 001 and 040 will be in group one, 041 to 080 in group 2 and 081 to 120 in group 3.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding in this study will be done in several steps as follows 1- Preparing 120 dressing packages that are the same in terms of appearance, type of packaging and color. 2- Using a table of random numbers to assign dressing packages to three treatment groups at random. 3- After assigning the dressings to three groups, we mark them with a label of 1 to 120. 4- The researcher delivers the dressing packages to the therapist and the therapist gives the patients from 1 to 120, respectively (only the researcher is aware of the number of dressings and which treatment group each dressing package belongs to, and therefore is blind. The study is valid because the therapist and patient are unaware of the nature of the treatment and dressing).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia University Of Medical sciences
Street address
No. 72 , Maad Alley , Ghandi Ave
City
Ahar
Province
East Azarbaijan
Postal code
5451665433
Approval date
2021-06-09, 1400/03/19
Ethics committee reference number
IR.UMSU.REC.1400.050

Health conditions studied

1

Description of health condition studied
hemodialysis patients
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis

Primary outcomes

1

Description
Catheter site infection
Timepoint

Three times at 48-hour intervals(At the time of initial dressing, the second and fourth day of dressing)

Method of measurement

checklist

2

Description

Bacterial colonization

Timepoint

Before intervention start and after 3rd time dressing

Method of measurement

skin culture from catheter location

Secondary outcomes

empty

Intervention groups

1

Description

The catheter site is disinfected with 10% povidone iodine and then washed and dried with normal saline, covered with a sterile dressing. The time required for rinsing with povidone iodine is 2 minutes. It will be washed and bandaged three times at intervals of 48 hours, and at each time the symptoms of local infection will be checked with a checklist, and then the correct way to take care of the catheter dressing and to observe the hygiene of the area will be taught. one liter povidone iodine from Pejhan Shimi Yazd Company will be used.

Category

Prevention

2

Description

Intervention group: To do the dressing with silver, according to the product catalog, first wash and dry the catheter site with washing serum and then wet the silver dressing with sterile water to have more and better silver release, then place it in the catheter site sterile and fix we do. Each group will be washed and bandaged three times at intervals of 48 hours. At each time, the symptoms of local infection will be checked with a checklist, and then the correct way to take care of the catheter dressing and observe the hygiene of the area will be taught. Eurofarm Silvermed adhesive silver absorbent dressing will be used.

Category

Prevention

3

Description

Intervention group:Rinse the catheter site with 2% chlorhexidine in 70% isopropyl for 30 seconds and wait for it to dry. It will then be sterilely dressed.Each group will be washed and bandaged three times at intervals of 48 hours. At each time, the symptoms of local infection will be checked with a checklist, and then the correct way to take care of the catheter dressing and observe the hygiene of the area will be taught. body prep solution from Behban Shimi company will be used that contains 2% chlorhexidine in 70% isopropyl alcohol

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

taleghani hospital of urmia

Full name of responsible person

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Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

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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
Oroumia University of Medical Sciences

Proportion provided by this source
40

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
Oroumia University of Medical Sciences
Full name of responsible person
Omid Pourmehr
Position
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Person responsible for updating data

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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

Unidentifiable data of individuals and related information available to others Researchers will be placed. Study protocol, data analysis program and Etc. will also be shared

When the data will become available and for how long

3 months after article publication

To whom data/document is available

Health care professionalists

Under which criteria data/document could be used

Data can be used to research and provide new solutions by citing the source

From where data/document is obtainable

Refer to this mail: pourmehr.omid@umsu.ac.ir Omid Pourmehr

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

Email to the applicant - Request from the Vice Chancellor for Research - If the information to the applicant is positive

Comments