Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation and comparison of the incidence of infection of repaired wound wounds with different dressing models in the emergency room

Protocol summary

Study aim

Determining and comparing the incidence of infection in repaired wound wounds with different dressing models in the emergency room

Design

Clinical trial on patients with limb ulcers after wound healing with three different dressing models (saline plain dressing group, vaseline dressing group and local tetracycline antibiotic gas dressing group) randomized without blinding, phase 3 on Rand function of Excel software was used on 150 randomized patients.

Settings and conduct

Patients after dressing the wound after randomization, are dressed with three different models and are examined for infection up to 7 days after the initial dressing for wound infection. t

Participants/Inclusion and exclusion criteria

Inclusion criteria:: Patients with limb wounds who are admitted to the emergency room of Khatam Al-Anbi Hospital for wound healing. Exclusion criteria: Patients receiving antibiotics while taking injectable antibiotics. Wounds that have healed in more than one layer. People with immunodeficiency / chronic corticosteroids / DM Wounds caused by animal bites Wounds with fractures People under the age of 18 and over the age of 60 People with chronic internal diseases (RF / RA / SLE / endocrine disorders) dirty wounds Wounds that have been repaired in other centers and referred to the emergency room of Khatam Al-Anbia Hospital for dressing. People with malnutrition, obesity and smoking

Intervention groups

A simple saline-impregnated dressing group, a vaseline dressing group, and a gas-dressing group impregnated with topical tetracycline antibiotics.

Main outcome variables

Wound infection (yes / no) Follow-up time (daily up to 7 days after wound healing)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054869N1**
Registration date: **2022-06-07, 1401/03/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-07, 1401/03/17**
Update count: **0**

Registration date

2022-06-07, 1401/03/17

Registrant information

Name

ali abdolrazaghnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3323 2890

Email address

ali.abdolrazaghnejad@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-06, 1401/03/16

Expected recruitment end date

2022-12-07, 1401/09/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the incidence of infection of repaired wound wounds with different dressing models in the emergency room

Public title
Evaluation and comparison of the incidence of infection of repaired wound wounds with different dressing models in the emergency room
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with limb wounds who are admitted to the emergency room of Khatam Al-Anbi Hospital for wound healing.
Exclusion criteria:
Patients receiving antibiotics while taking injectable antibiotics. Wounds that have healed in more than one layer. People with immunodeficiency / chronic corticosteroids / DM Wounds caused by animal bites Wounds with fractures People with chronic internal diseases (RF / RA / SLE / endocrine disorders) Clearly dirty wounds Complex, crushed and twisted wounds The size of the wounds is more than 20 cm Wounds that have been repaired in other centers and referred to the emergency room of Khatam Al-Anbia Hospital for dressing. Patients who have referred for wound healing for more than 6 hours People with malnutrition, obesity and smoking
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
.Random allocation of patients to two groups is done by permuted block stratified randomization. In this way, first, the eligible patients are classified according to age and sex, respectively. Then, based on 6 blocks (consisting of three groups A, B and C and two repetitions for each) that are randomly selected from all possible modes of permutations, they are assigned to the desired group. These blocks are created using R statistical software version 4.0.2. These codes are located in a sealed package to hide the allocation in the envelope, which will be assigned to patients in order. Matching The two groups are matched in terms of age and sex (Frequency matching) using the permutation block stratified randomization method.
Blinding (investigator's opinion)
Double blinded
Blinding description
The outcome assessor and data analyst are unaware of the types of interventions (different dressing models).
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Daneshgah blvd
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9815733169
Approval date
2022-04-17, 1401/01/28
Ethics committee reference number
IR.ZAUMS.REC.1401.062

Health conditions studied

1

Description of health condition studied
Sutured wound infection
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Wound infection (having or not having)
Timepoint
Daily up to 7 days after the initial dressing
Method of measurement
check list

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dressing with sterile gauze

impregnated with saline. Put a layer of 0.9% saline-impregnated gas on the wound and then put a layer of dry sterile gas on it and fix it on the skin with glue. We change the dressing for up to 7 sessions daily.

Category

Prevention

2

Description

Intervention group: Gas stove to Vaseline. Put a layer of Vaseline impregnated gas on the wound and then put a layer of dry sterile gas on it and then fix it on the wound with glue. We change the dressing up to 7 times a day.

Category

Prevention

3

Description

Intervention group: Gas tetracycline-impregnated topical antibiotic gas. Apply a layer of tetracycline topical antibiotic-impregnated gas to the wound, then apply a layer of dry sterile gauze, and then fix the adhesive to the wound. We change the dressing up to 7 times a day.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-al-anbia hospital

Full name of responsible person

ali abdolrazaghnejad

Street address

khatam square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

normohammad bakhshani

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

ali abdolrazaghnejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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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
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
All data is potentially shareable after unidentifiable individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
The data will be available to researchers, including in laboratory and scientific institutions.
Under which criteria data/document could be used
In order to use the data in research work and after sending the request, if the researcher agrees, the data responsible will be provided to the applicant.
From where data/document is obtainable
Correspond with the responsible researcher (Ali Abdolrazaqnejad) via email.
What processes are involved for a request to access data/document
After submitting the request, the applicant will have access to the data up to 1 month after the request, if he / she meets the conditions.
Comments