Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effects of amnion and normal saline on healingand wound pain in patients with second-degree pressure ulcers

Protocol summary

Study aim
Determining the effect of dressing with amniotic membrane and usual dressing on healing rate and wound pain in patients with second degree pressure ulcer.

Design
Clinical trial with control group, double blind, randomized, on 58 patients. A coin toss will be used for randomization.

Settings and conduct
The location of the study is the internal and ICU departments of the Vali-e-Asr hospital in Arak 2- The study population: All patients with second-degree pressure ulcers 3- The study will be conducted double blind and the assessor and the patient will not be aware about the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having grade 2 pressure ulcers; having desire to participate in research; Being able to answer questions. Non-inclusion criteria: contamination of patient's wound with contaminating substances; using a substance other than drinking water on the wound; Having symptomatic infection in different parts of the body

Intervention groups
Intervention group: amniotic dressing, After washing the wound with normal saline, a layer of amniotic membrane is placed on the wound and covered with two or three layers of sterile gauze and bandaged with a sterile bandage. Control group: Dressing with normal saline, After washing the wound with normal saline, the wound is covered with two or three layers of sterile gauze and bandaged with a sterile bandage.

Main outcome variables
Healing rate, pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180715040478N3**
Registration date: **2023-01-31, 1401/11/11**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-31, 1401/11/11**
Update count: **0**

Registration date
2023-01-31, 1401/11/11

Registrant information

Name
Azam Malekhoseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-27, 1401/05/05

Expected recruitment end date
2023-07-27, 1402/05/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of amnion and normal saline on healingand wound pain in patients with second-degree pressure ulcers

Public title
The effect of amnion on the healing and second degree pressure ulcer pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants have grade 2 pressure ulcer Willingness to participate in research Be able to answer questions
Exclusion criteria:
The patient's wound is contaminated with contaminating substances. Have used a substance other than drinking water on the wound Have symptomatic infection in different parts of the body
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples were selected from the study population by Convenience Sampling method and then by Simple Random allocation method (coin toss) ten people were placed in each group, after that the background characteristics of the patients were evaluated in each group. The next patient who entered the study was entered into a group that minimized the overall difference between the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted in a double-blind manner, and the evaluator and the patient will not know about the type of treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Khomein University of Medical Sciences
Street address
Azadi Street
City
Khomein
Province
Markazi
Postal code
38818-58573
Approval date
2022-08-24, 1401/06/02
Ethics committee reference number
IR.KHOMEIN.REC.1401.007

Health conditions studied

1

Description of health condition studied
Bed sore
ICD-10 code
L89
ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
size of wound
Timepoint
The first, seventh and fourteenth days
Method of measurement
Using tape measure

2

Description
The amount of pain
Timepoint
The first, seventh and fourteenth days
Method of measurement
Visual Analogue Scale of Pain

Secondary outcomes

empty

Intervention groups

1

Description
The experimental group will be treated with amniotic membrane. In this way, after washing the wound with normal saline, a layer of amniotic membrane is placed on the wound and covered with two or three layers of sterile gauze and bandaged with a sterile bandage.
Category
Treatment - Drugs

2

Description
Control group: They will be treated with normal saline, so the wound is covered with two or three layers of sterile gauze and bandaged with a sterile bandage daily after washing the wound with normal saline.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-Asr Hospital of Arak
Full name of responsible person
Azam malekhoseini
Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mahdi Salehi
Street address
A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak
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38481-7-6341
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pr_valieasr@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Azam Malekhoseini
Position
Coach
Latest degree
Master
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Nursery
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Person responsible for updating data

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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