

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effects of amnion and normal saline on healing and 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)

Phone

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Email address

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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 healing and 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

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Khomein

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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

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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

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A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak

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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

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

Other areas of specialty/work

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