Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of egg white formulation on bed sore healing

Protocol summary

Study aim
The effect of egg white formulation on bed sore healing
Design
Clinical trial with an intervention group and a control group, three-sided, randomized, phase three on 78 patients, randomization will be performed with WinPepe software.
Settings and conduct
The subjects, researchers and analysts were all blind in this study. The method of blinding is that the drug maker numbers the container containing the drug and the placebo with numbers 1 and 2 . The researcher uses each number for an intervention or control group while being unaware of the contents of the container. This study is performed in Imam and Golestan hospitals of Ahvaz.
Participants/Inclusion and exclusion criteria
1. Age over 18 years 2. Clinical diagnosis of grade 2 and 3 pressure ulcers 3. Hospitalized in the intensive care unit of Golestan and Imam hospitals in Ahvaz 4. Antibiotic use was the same in both groups 5. Absence of cancer 6. Do not use immunosuppressants 7. Absence of chronic diseases that are in the process of treatment of diseases such as disease, severe diseases, lupus, rheumatoid arthritis and kidney failure, which is determined by the patient's medical history and file.
Intervention groups
The intervention includes dressing patients' wounds according to the procedure of changing the hospital dressing. Egg white formula is used in the intervention group and placebo in the control group with phenytoin cream or camphile depending on the doctor's prescription and the wound is bandaged. Wounds are then examined at the end of each week for four weeks according to pressure criteria. Sampling is done by the researcher. Scoring is done by three observers, two observers with direct observation and one with photo.
Main outcome variables
Reducing the duration and treatment costs of pressure ulcers, increasing the quality of life of patients.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220522054960N1**
Registration date: **2022-06-12, 1401/03/22**
Registration timing: **prospective**

Last update: **2022-06-12, 1401/03/22**
Update count: **0**
Registration date
2022-06-12, 1401/03/22

Registrant information
Name
Atefeh Tadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 38 3372 4813
Email address
atefehtadi@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-06-22, 1401/04/01
Expected recruitment end date
2022-08-23, 1401/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of egg white formulation on bed sore healing

Public title
The effect of egg white formulation on bed sore healing
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Age over 18 years 2. Clinical diagnosis of grade 2 and 3 pressure ulcers 3. Hospitalized in the intensive care unit of Golestan and Imam Ahvaz hospitals 4. Antibiotic use was the same in both groups 5. No cancer 6. Do not use immunosuppressants 7. Do not have chronic diseases that affect the wound healing process, such as diabetes, severe vascular disease, lupus, rheumatoid arthritis and kidney failure, which is determined by the patient's medical history and record.
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment of patients to intervention and control groups will be done by block random method using 6 blocks. In each block, 3 people will be in the intervention group and 3 people in the control group, but the order of placement will be It will be a random form that will be done with WinPepi software.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the manufacturer of the formulation numbered the container containing the drug formula and the placebo, while none of the participants in the study included the researcher, clinical caregiver, outcome assessor, data analyst, and content monitoring committee. Every dish is unknowingly studied.
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Golestan Alley, Esfand St., Ahvaz University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2022-05-07, 1401/02/17
Ethics committee reference number
IR.AJUMS.REC.1401.066

Health conditions studied

1

Description of health condition studied
Compression ulcer, which is a disorder of skin cohesion, occurs due to the compression of the soft tissue between the skeletal joints and an external surface such as the bed or chair.
ICD-10 code
L89
ICD-10 code description
Pressure ulcer

Primary outcomes

1

Description
Wound healing is the healing and return of complete health to the damaged tissue in this study Acupressure wound healing means that according to the standard dressing checklist, the score given to the wound is reduced compared to the initial score (week zero).
Timepoint
End each week for four weeks
Method of measurement
Wound measurement and control tools, which consist of three criteria: wound size, amount of secretions and type of tissue, examine the wound and determine the wound healing status by combining these three criteria. In this checklist, the extent of the wound is 10-0. The amount of wound discharge is 0-3 and the type of wound tissue is 0-4. A score of zero indicates wound healing and a highest score of 17 indicates wound healing.

Secondary outcomes

empty

Intervention groups

1

Description

This study examined second- and third-degree wounds and none of the patients are deprived of their main treatment, which is a daily dressing with phenytoin ointment or camphil dressing. The treatment protocol is such that patients' wound dressings are changed daily according to the hospital dressing routine. In this way, after preparing the dressing changing equipment, including sterile gloves, sterile gauze, washing serum, sterilized changing dressing set and hand glue with washed water and soap, then the previous dressing is removed along with the process of changing the previous dressing position. The wound is examined ، After wearing sterile gloves, the wound is washed with serum and dried with sterile gauze. Then, the egg white formulation is used in the intervention group and placebo in the control group with phenytoin cream or camphile, depending on the doctor's prescription. The wound is bandaged. Wounds are then examined at the end of each week for four weeks according to push criteria. Using the push tool, three criteria of wound size, amount of secretions and type of tissue formed in the wound are detected and scored. Sampling of samples in both intervention and control groups is performed by the researcher. Because environmental factors may affect the observer, two observers are used to score in the observed position. In order to prevent bias from the wounds of patients in the treatment process, digital photos are taken and the photos are examined by the third observer, who is not aware of the type of dressing, in terms of the healing process. The observer is required to read the completed questionnaire for patients as soon as possible after observation, in order to avoid inconsistencies and ambiguities due to the time interval between observation and study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Meisam Moezi

Street address

Golestan hospital, Golestan

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6135715794

Phone

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Email

golestanhospital@ajums.ac.ir

2

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Reza Akhondzadeh

Street address

Imam khomeini hospital. Azadegan Blvd

City

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Province

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7311161936

Phone

+98 61 3292 3985

Email

himam@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mrs Zakerkish

Street address

Ahwaz University of Medical Sciences, Golestan.

City

Ahvaz

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6135715794

Phone

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info@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Atefeh Tadi

Position
Graduate student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 10, Karun 3 Complex, between Dey and Bahman St, Shahrivar St, Golestan.

City
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
A large part of the data such as information about the main outcome, how to do, etc. can be shared.

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
All researchers

Under which criteria data/document could be used
By observing the ethics of research

From where data/document is obtainable
Atefeh Tadi atefehtadi@yahoo.com

What processes are involved for a request to access data/document
Send the request to the email and receive the answer within two weeks after authentication.

Comments