

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

Khuzestan

##### 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

golestanhospital@ajums.ac.ir

### 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

**City**  
Ahvaz

**Province**  
Khouzestan

**Postal code**  
6135715794

**Phone**  
+98 61 3374 3009

**Email**

### 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**  
Ahvaz

**Province**  
Khouzestan

**Postal code**  
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**  
Ahvaz University of Medical Sciences, Golestan.

**City**  
Ahvaz

**Province**  
Khouzestan

**Postal code**  
6135715794

**Phone**  
+98 61 3311 4114

**Email**  
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**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135935700

**Phone**

+98 38 3372 4813

**Email**

atefehTadi@yahoo.com

## Person responsible for scientific 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**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135935700

**Phone**

+98 38 3372 4813

**Email**

atefehTadi@yahoo.com

## Person responsible for updating data

### 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**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135935700

**Phone**

+98 38 3372 4813

**Email**

atefehTadi@yahoo.com

## 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**