Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy of a Smart Nano-Wound Dressing in Pressure Ulcer Healing: A Randomized Clinical Trial

Protocol summary

Study aim
Treatment of patients with pressure ulcers

Design
Study Design Study Type: Randomized, Double-Blind, Controlled Clinical Trial (RCT), Multicenter. Study Duration: 14 days of treatment + 4 weeks of follow-up. Randomization: Randomized Block Design (1:1). Inclusion Criteria - Patients aged 18 to 80 years. - Pressure ulcer grade II, III, or IV (according to NPUAP) at least 4 weeks before study entry. - Wound size 1 to 15 cm2. - Patient with stable hemodynamic status. Exclusion Criteria - Patients with severe wound infection requiring surgery. - Patients with severe gangrene or necrosis that cannot be debridement. - Cancer, immunodeficiency, or advanced renal failure. Method of Use: 1. First, disinfect and clean the areas around the wound (standard wound washing and controlled debridement). 2. Place the dressing on the wound, making sure that it has maximum contact with the wound. 3. Apply a suitable secondary dressing over this dressing. 4. Every 3-5 days. 5. Store at room temperature and avoid direct sunlight. Control group (standard dressing) • Foam or hydrogel dressing, changed every 2-3 days. • Other wound care is the same as in the experimental group. - Evaluation of results - Statistical analysis

Settings and conduct
The study is double-blind and conducted at Iran and Bam University of Medical Sciences .

Participants/Inclusion and exclusion criteria
People with bedsores (pressure ulcers) aged 18 to 80 years with grade II, III, or IV pressure ulcers whose wound diameter is 1-15 square centimeters and who have signed a written informed consent form that allows for follow-up and have the necessary cooperation in taking medication. Having one or more pressure ulcers with the largest wound diameter less than 15 centimeters.

Intervention groups
Experimental group: NWD treatment. Control group: standard treatment

Main outcome variables
Rate of wound closure during treatment. Healing time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250610066159N2**
Registration date: **2025-10-17, 1404/07/25**
Registration timing: **prospective**

Last update: **2025-10-17, 1404/07/25**
Update count: **0**

Registration date
2025-10-17, 1404/07/25

Registrant information

Name
Ghazaleh Chizarifard

Name of organization / entity
Bam University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-11-21, 1404/08/30

Expected recruitment end date
2026-11-21, 1405/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of a Smart Nano-Wound Dressing in Pressure Ulcer Healing: A Randomized Clinical Trial

Public title
Treatment of Pressure Ulcers with Nano-Melissa (Lemon Balm)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with pressure ulcers (decubitus ulcers/bedsores) Participants aged between 18 and 80 years Participants who are willing and able to comply with the use of the smart wound dressing Participants who provide signed written informed consent
Exclusion criteria:
Not applicable.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization sequence was generated by an independent statistician using R software. Block randomization with variable block sizes (4 and 6) was applied to prevent predictability. The allocation list was concealed using sequentially numbered, opaque, sealed envelopes (SNOSE). After baseline assessment, each participant’s envelope was opened by a nurse not involved in sequence generation, and the assigned dressing type was applied accordingly. The study was assessor-blinded; outcome assessors and the data analyst were unaware of group allocation.
Blinding (investigator's opinion)
Double blinded
Blinding description
A stratified randomization method will be used. Patients will be divided into two groups (intervention and control) based on the presence of pressure ulcers, and randomization within each group will be performed using a pre-prepared randomization list. This list will be generated prior to the start of the study. The principal investigator will introduce the selected patients to the clinical caregiver and the outcome assessor (a nursing specialist), who will be responsible for the process. According to the list, wound treatment will be carried out using either the nano-smart wound dressing or the standard wound dressing.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committees Bam University of Medical Science
Street address
Shahid Rajaei Boulevard- Sardarān-e Shahid Square- Bam- Iran
City
Bam
Province
Kerman
Postal code
38R9+498
Approval date
2025-05-18, 1404/02/28
Ethics committee reference number
IR.MUBAM.REC.1404.013

Health conditions studied

1

Description of health condition studied
Pressure ulcer- Pressure ulcer- Nano wound dressing
ICD-10 code
L89.002
ICD-10 code description
Pressure ulcer of unspecified elbow, stage 2, stage 3 and Stage IV

2

Description of health condition studied
Pressure ulcer
ICD-10 code
L89.003
ICD-10 code description
Pressure ulcer of unspecified elbow, stage 3

3

Description of health condition studied
Pressure ulcer
ICD-10 code

L89.004

ICD-10 code description

Pressure ulcer of unspecified elbow, stage 4

Primary outcomes

1

Description

The incidence of wound infection or recurrence of necrosis

Timepoint

Days 3, 7, and 14

Method of measurement

A visual observation–based scoring system

2

Description

Intensity of pain

Timepoint

Days 3, 7, and 14

Method of measurement

Assessment by visual inspection

3

Description

The extent of changes in IL-6, TNF-α, CRP.

Timepoint

Days 3, 7, and 14

Method of measurement

Biochemical analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with pressure ulcers treated with the nano-smart wound dressing alongside standard wound care

Category

Treatment - Devices

2

Description

Control group: Patients with pressure ulcers treated with standard wound dressing alongside standard wound care

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Bam University of Medical Sciences

Full name of responsible person

shirin nasri mohajeri

Street address

Shahid Rajaei Boulevard- Sardarān-e Shahid Square- Bam- Iran

City

Kerman

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7661771967

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Dr.shirin.nasri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pajoohesh BAMA Co.

Full name of responsible person

Dr. Ghazaleh Chizari Fard

Street address

Unit 9- No. 42- Maleki Street- Golbarg Sharghi- Bagheri Highway- Tehranpars- Tehran- Iran

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1651897463

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Email

chizarigh@gmail.com

Web page address

https://www.pajooheshbama.com/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pajoohesh BAMA Co.

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity
Pajoohesh BAMA Co.

Full name of responsible person
Ghazaleh Chizari Fard

Position
CEO

Latest degree
Ph.D.

Other areas of specialty/work
Medical Nanotechnology

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Unit 9, No. 42, Maleki Street, East Golbarg, Bagheri Highway, Tehranpars.

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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
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
- Results of the effectiveness of smart nanowound dressing in pressure ulcer healing: a randomized clinical trial - Results and data will be published after de-identification of individuals.

When the data will become available and for how long
1 year after the end of the study

To whom data/document is available
Researchers and people working in the fields of medicine and medical engineering

Under which criteria data/document could be used
The data will be accessible to other authorized persons upon request and permission from the project implementer.

From where data/document is obtainable
The data will be accessible to the parties upon request from the project administrator.

What processes are involved for a request to access data/document
1- Written request from the project manager 2- Check the applicant's qualifications 3- Approval by the manager and colleagues 4- Send approval and provide access to

the applicant

Comments