

# 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 cm<sup>2</sup>. - 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)

##### Phone

+98 21 7772 7495

##### Email address

chizarigh@gmail.com

##### 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- $\alpha$ , 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

#### Province

Kerman

#### Postal code

7661771967

#### Phone

+98 913 397 9453

#### Email

Dr.shirin.nasri@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Pajooresh 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1651897463

##### Phone

+98 912 485 8986

##### Email

chizarigh@gmail.com

##### Web page address

<https://www.pajooreshbama.com/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Pajooresh 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

**Street address**

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Pajoohesh BAMA Co.

**Full name of responsible person**

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**Position**

CEO

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Pajoohesh BAMA Co.

**Full name of responsible person**

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**Position**

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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**