

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Smart Nano-Wound Dressing for Wound Healing in Diabetic Patients: A Randomized Controlled Trial

#### Protocol summary

##### Study aim

This study aims to evaluate the efficacy of a synthesized nano-wound dressing in the treatment of diabetic wounds

##### Design

Study Procedure: Test Group: The surrounding area of the wound will be disinfected and cleaned (standard wound washing and controlled debridement). The nano-wound dressing will be applied to the wound, ensuring maximum contact with the wound surface. A suitable secondary dressing will be placed over the nano-wound dressing. The dressing will be changed every 2 to 3 days. The patient will be kept at room temperature to avoid direct sunlight exposure. Control Group: Standard wound dressings (gauze, foam, or hydrogel) will be used. Dressings will be changed every 2 to 3 days. All other wound care procedures will be the same as in the test group. Data Analysis: At the end of each stage, outcome evaluation and statistical analysis will be performed.

##### Settings and conduct

The study will be carried out as a double-blind, multicenter trial at institutions affiliated with Iran University of Medical Sciences and Bam University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18–80 years with diabetic wounds of varying grades and sizes between 1–15 cm<sup>2</sup>, who have provided written informed consent for follow-up and demonstrate compliance with the use of the nano-wound dressing. Exclusion criteria: Participants who do not meet any of the above requirements or fail to comply during the study.

##### Intervention groups

Intervention group: Patients with diabetic wounds treated with the nano-wound dressing alongside standard wound care. Control group: Patients with diabetic wounds treated with the standard wound dressing alongside standard wound care.

##### Main outcome variables

Primary outcomes: Wound closure rate and wound healing duration.

#### General information

##### Reason for update

##### Acronym

SNWD-DM

##### IRCT registration information

IRCT registration number: **IRCT20250610066159N1**

Registration date: **2025-10-12, 1404/07/20**

Registration timing: **prospective**

Last update: **2025-10-12, 1404/07/20**

Update count: **0**

##### Registration date

2025-10-12, 1404/07/20

##### 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**

Smart Nano-Wound Dressing for Wound Healing in Diabetic Patients: A Randomized Controlled Trial

**Public title**

Investigation of the Effects of Lemon Balm (*Melissa officinalis*) on Diabetic Wounds

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with diabetic wounds Participants aged between 18 and 80 years Participants who demonstrate adequate compliance with the use of the wound dressing throughout the treatment period Participants who have provided written informed consent prior to enrollment

**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**

Participants were assigned to the treatment and control groups using block randomization (block size = 4) generated with R software. The randomization sequence was prepared and coded by a researcher not involved in the study execution. The trial was conducted in a double-blind manner, so that both participants and outcome assessors were unaware of group allocation. This study was designed as a multicenter, controlled, randomized clinical trial.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A stratified randomization method will be used. Patients will be divided into two groups based on the presence of diabetic wounds and whether they will receive the specialized dressing (intervention) or the standard dressing (control). Randomization within each group will then be performed using a pre-prepared randomization list. This list will be generated by the physician prior to the study. The principal investigator will introduce the selected patients to the clinical caregiver and the

outcome assessor (a nursing specialist) responsible for the process. According to the list, wound treatment will be carried out using either the nano-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 committee of 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.1404.012

**Health conditions studied****1****Description of health condition studied**

Diabetic wound

**ICD-10 code**

E11.622

**ICD-10 code description**

Type 2 diabetes mellitus with other skin ulcer

**Primary outcomes****1****Description**

The primary outcome variable is wound healing, measured as the reduction in wound area in patients treated with the smart nano-wound dressing. Wound area will be assessed using graph paper measurement or digital imaging software at specified time points. Changes in wound area between the treatment and control groups will be compared as the main indicator of study efficacy.

**Timepoint**

Assessments will be conducted on days 0, 7, 14, and 28,

with the schedule extended as needed until complete wound healing.

#### **Method of measurement**

Wound evaluation will be performed through visual inspection and by measuring the wound surface area.

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Smart nanofiber wound dressing containing 1% Melissa officinalis extract: Patients in the intervention group will use a smart nanofiber wound dressing containing 1% Melissa officinalis extract, produced by the company "Pajohesh Ba Ma". The dressing will be changed every 6 days by a trained nurse. The total treatment duration is two weeks. During each dressing session, patients will receive the necessary training on wound care. Additional materials include bandage and adhesive tape.

#### **Category**

Treatment - Devices

### **2**

#### **Description**

Control group: Standard wound dressing:  
<https://chatgpt.com/c/68eb66d9-7538-832e-bb06-9d1e7e28e660#:~:text=Patients%20in%20the%20control%20group%20will%20use%20standard%20wound%20dressing.%20The%20dressing%20will%20be%20changed%20every%206%20days%20according%20to%20standard%20clinical%20guidelines.%20The%20total%20treatment%20duration%20is%20two%20weeks%2C%20and%20all%20patients%20will%20receive%20wound%20care%20education%20from%20a%20trained%20nurse.>

#### **Category**

Treatment - Devices

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Bam university of medical sciences

##### **Full name of responsible person**

Dr. Shirin Nasri Mohajeri

##### **Street address**

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

##### **City**

Bam

##### **Province**

Kerman

##### **Postal code**

7661771967

##### **Phone**

+98 913 397 9453

##### **Email**

Dr.shirin.nasri@gmail.com

### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Iran university of medical sciences

##### **Full name of responsible person**

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/>

## **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

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<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**

Dr. Ghazaleh Chizari Fard

**Position**

CEO

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Nanotechnology

**Street address**Unit 9, No. 42, Maleki Street, Golbarg Sharghi,  
Bagheri Highway, Tehranpars, Tehran, Iran**City**

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**Province**

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**Web page address**<https://www.pajooheshbama.com/%d9%85%d8%af%b%8c%d8%b1-%d8%b9%d8%a7%d9%85%d9%84/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Pajoohesh BAMA Co.

**Full name of responsible person**

Dr. Ghazaleh Chizari Fard

**Position**

CEO

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Nanotechnology

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**Person responsible for updating data****Contact****Name of organization / entity**

Pajoohesh BAMA Co.

**Full name of responsible person**

Dr. Ghazaleh Chizari Fard

**Position**

CEO

**Latest degree**

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**Other areas of specialty/work**

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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**Undecided - It is not yet known if there will be 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**Production of smart nanowound dressings in wound  
healing in diabetic patients: A randomized clinical trial**When the data will become available and for how long**

1 year after the end of the clinical study

**To whom data/document is available**

Medical researchers

**Under which criteria data/document could be used**For future studies in the field of wound healing and with  
permission from the project manager**From where data/document is obtainable**Permission must be obtained in writing from the project  
manager.

**What processes are involved for a request to access data/document**

1- Request access to the project implementer 2- Review by the implementer and the partner team 3- Approval of

the request by the implementer 4- Permission to access the data

**Comments**