

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the effectiveness of the three methods: healing with dry amniotic dressing, dressing with platelet derived growth factor, and conventional surgical debridement on the improvement of diabetic foot ulcer: a randomized clinical trial

Protocol summary

Study aim

To compare the effectiveness of the three methods: healing with dry amniotic dressing, dressing with platelet derived growth factor, and conventional surgical debridement on the improvement of diabetic foot ulcer

Design

This is a randomized clinical trial, phase II, in which 123 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with diabetic foot ulcer referring to the Imam Hussein Hospital in Tehran city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years, Diabetic foot ulcer with dimension between 1 and 10 cm, Level 1 or 2 based on Vegner scale, HbA1c less than 8, Suitable tissue circulation, Exclusion criteria: Pregnancy or breastfeeding, Osteomyelitis, Malnutrition, Chemotherapy or radiotherapy, Malignancy, Autoimmune diseases, Renal diseases needing dialysis, Immunosuppressive drugs

Intervention groups

Intervention group 1: Wound irrigation and then healing with dry amniotic dressing daily for 10 weeks
Intervention group 2: Wound irrigation and then dressing with platelet-derived growth factor daily for 10 weeks
Control group: Wound irrigation and then conventional surgical debridement daily for 10 weeks

Main outcome variables

Primary outcome: Improve diabetic foot ulcers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N352**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **prospective**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-06-04, 1399/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title

Comparison of the effectiveness of the three methods: healing with dry amniotic dressing, dressing with platelet derived growth factor, and conventional surgical debridement on the improvement of diabetic foot ulcer: a randomized clinical trial

Public title

Comparison of the effectiveness of the three methods: healing with dry amniotic dressing, dressing with platelet derived growth factor, and conventional surgical debridement on the improvement of diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 70 years, Diabetic foot ulcer with dimension between 1 and 10 cm, Level 1 or 2 based on Vegner scale, HbA1c less than 8, Suitable tissue circulation,

Exclusion criteria:

Pregnancy or breastfeeding, Osteomyelitis, Malnutrition, Chemotherapy or radiotherapy, Malignancy, Autoimmune diseases, Renal diseases needing dialysis, Immunosuppressive drugs

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Shahid Beheshti University of Medical Sciences, Danshjou Bul.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.SBMU.MSP.REC.1398.545

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description

Improve diabetic foot ulcers

Timepoint

In weeks 4, 6, 8 and 10 after the intervention

Method of measurement

With clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Wound irrigation and then healing with dry amniotic dressing daily for 10 weeks

Category

Treatment - Other

2

Description

Intervention group 2: Wound irrigation and then dressing with platelet derived growth factor daily for 10 weeks

Category

Treatment - Other

3

Description

Control group: Wound irrigation and then conventional surgical debridement daily for 10 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital in Tehran city

Full name of responsible person

Dr Majid Tajik

Street address

Imam Hussein Hospital, Shahid Madani Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Majid Tajik

Position

Resident of General Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available