

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Clinical trial of the effect of probiotic supplementation compared with the placebo on wound healing and metabolic profiles in patients with diabetic foot

Protocol summary

Study aim

The aim of this study is to determine the effects of probiotic supplementation on wound healing and metabolic profiles in patients with diabetic foot.

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial

Settings and conduct

60 patients with diabetic foot of eligible and referred to Rouhani Clinic affiliated to Babol University of Medical Sciences, Babol, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Patients with diabetic foot and aged 40 to 85 years will be included in this study.

Intervention groups

Patients will be assigned to receive either probiotic supplements (intervention group: n=30) and placebo (control group: n=30).

Main outcome variables

Mean ulcer area and metabolic profiles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201603085623N68**

Registration date: **2016-03-22, 1395/01/03**

Registration timing: **retrospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **1**

Registration date

2016-03-22, 1395/01/03

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2016-02-15, 1394/11/26

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of probiotic supplementation compared with the placebo on wound healing and metabolic profiles in patients with diabetic foot

Public title

Effect of supplementation in treatment of patients with diabetic foot

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic foot Ulcer Aged 40 to 85 years

Exclusion criteria:

Grade 3 DFU with abscess formation and osteomyelitis
History of diseases which influence the development of diabetic foot Ulcer including prior history of wounds
Pregnant and breastfed patients Taking probiotic supplements and other forms of probiotics including probiotic yogurt, kefir and other fermented foods Taking prebiotic Antioxidant and/or anti-inflammatory supplements, such as vitamin E, vitamin C and omega-3 fatty acids Change in consuming medications throughout the study

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either probiotic supplements (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Rouhani Hospital affiliated to Babol University of Medical Science, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

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Ganjafrooz Street, Babol

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Babol

Province

Mazandaran

Postal code

۴۷۱۷۶-۴۷۷۴۵

Approval date

2016-02-14, 1394/11/25

Ethics committee reference number

IR.MUBABOL.REC.1394.308

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

Diabetic foot

ICD-10 code

E11 and E1

ICD-10 code description

Non-insulin-dependent diabetes mellitus and with peripheral circulatory complications

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

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

2**Description**

Healing of diabetic foot ulcer

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Decrease of the wound size relative to original size: ulcer length (cm), ulcer width (cm), Ulcer depth (cm)

Secondary outcomes**1****Description**

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

5

Description

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

7

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

8

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

10

Description

HbA1c

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Biochemical kit

11

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

12

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

13

Description

Erythrocyte sedimentation rate

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Westergren method

Intervention groups

1

Description

Intervention group: Probiotic supplements containing four strains of *Lactobacillus acidophilus* (2×10⁹ CFU/g),

Lactobacillus casei (2×10⁹ CFU/g), Lactobacillus Fermentum (2×10⁹ CFU/g) and Bifidobacterium bifidum (2×10⁹ CFU/g), daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo, daily, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani Clinic

Full name of responsible person

Masomeh Bayani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

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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

Babol 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Nutritionist

Latest degree

Ph.D.

Other areas of specialty/work

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Phone

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