Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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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

Street address
Ganjafrooz Street, Babol

City
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

Full name of responsible person

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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

Nutrition

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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