

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of probiotic *saccharomyces boulardii* on anthropometric indices, functional status, pain and quality of life and serum indices of inflammation and oxidative stress in overweight and obese patients with knee osteoarthritis

Protocol summary

Study aim

Determination of the effect of probiotic *saccharomyces boulardii* on anthropometric indices, functional status, pain and quality of life and serum indices of inflammation and oxidative stress in overweight and obese patients with knee osteoarthritis

Design

A prospective concealed randomized triple-blind placebo-controlled parallel-group clinical trial of 70 patients, enrolled between September 2019 and March 2020

Settings and conduct

Patients attending outpatient clinics at the Emam Reza Hospital of Tabriz University of Medical Sciences who have been diagnosed with primary mild to moderate knee osteoarthritis will be invited to an initial assessment to determine if they meet the inclusion and exclusion criteria. Then the patients will be randomly assigned to receive either the probiotic supplement or the placebo for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients diagnosed with knee osteoarthritis according to the diagnostic criteria of American College of Rheumatology, being 40 years of age or older, chronic knee pain for the last 3 months, radiologic confirmation of knee osteoarthritis (Kellgren-Lawrence grade II or III) and body mass index in the range of 25 to 40 kg/m² Exclusion criteria: previous knee surgery, rheumatoid arthritis, metabolic disorder (such as diabetes and cancer), liver or kidney failure, use of corticosteroids and/or intra-articular injections during the preceding 3 months, use of fish oils and glucosamine, participation in a weight loss program in the preceding 6 months, unable to express their pain (such as those with any mental condition)

Intervention groups

Intervention group 1: probiotic capsules once daily for 12

weeks, each capsule contains 250 mg of *Saccharomyces boulardii* (1010 CFU) Intervention 2: placebo capsules once daily for 12 weeks

Main outcome variables

Functional status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N4**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **prospective**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Neda Dolatkhan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic saccharomyces boulardi on anthropometric indices, functional status, pain and quality of life and serum indices of inflammation and oxidative stress in overweight and obese patients with knee osteoarthritis

Public title

Probiotic saccharomyces boulardi in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with knee osteoarthritis according to the diagnostic criteria of American College of Rheumatology Being 40 years of age or older Chronic knee pain for the last 3 months Radiologic confirmation of knee osteoarthritis (Kellgren–Lawrence grade II or III) Body mass index in the range of 25 to 40 kg/m²

Exclusion criteria:

Previous knee surgery Rheumatoid arthritis Metabolic disorder (such as diabetes and cancer) Liver or kidney failure Use of corticosteroids and/or intra-articular injections during the preceding 3 months Use of fish oils and glucosamine Participation in a weight loss program in the preceding 6 months Unable to express their pain (such as those with any mental condition)

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with block sizes of four and eight using RASS software and the allocation ratio of 1:1. Randomization and allocation concealment will be carried out for both the researchers and participants, by a trained staff at the research center.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Main investigators, caregivers, outcome assessors, data analyser and the participants will be all masked to treatment assignment throughout the study. Since the supplements and placebo capsules have similar packaging, patients and researchers will be unaware of the content of the package until the end of study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5169865986

Approval date

2019-07-29, 1398/05/07

Ethics committee reference number

IR.TBZMED.REC.1398.506

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

Knee osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Osteoarthritis, unspecified site

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

Weight

Timepoint

Weight measurement at baseline (before intervention) and 6 and 12 weeks after intervention

Method of measurement

Seca 813 bt digital scale

2

Description

Functional status

Timepoint

Functional status evaluation at baseline (before intervention) and 6 and 12 weeks after intervention

Method of measurement

Western Ontario and McMaster (WOMAC) Index

3

Description

Pain intensity

Timepoint

Pain intensity measurement at baseline (before intervention) and 6 and 12 weeks after intervention

Method of measurement

Visual Analogue Scale

4

Description

Quality of life

Timepoint

Quality of life evaluation at baseline (before intervention) and 12 weeks after intervention

Method of measurement

36-Item Short Form Survey (SF-36)

5

Description

Inflammatory indices

Timepoint

Inflammatory indices measurement at baseline (before intervention) and 12 weeks after intervention

Method of measurement

Biochemical methods

6

Description

Oxidative stress indices

Timepoint

Oxidative stress indices measurement at baseline (before intervention) and 12 weeks after intervention

Method of measurement

Biochemical methods

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will take BioDigest capsules once daily for 12 weeks. Each capsule contains 250 mg of SB (1010 CFU) plus a lactose filler and a magnesium stearate lubricant. The intervention

capsules will be produced and packed by Takgene Pharmaceutical Company, Tehran, Iran.

Category

Treatment - Drugs

2

Description

Control group: The control group will take placebo capsules once daily for 12 weeks. In terms of shape, size, taste, smell, and other exfoliation characteristics, they are quite similar to the Biodigest capsules except that they do not contain any microorganisms. The placebo capsules will also be produced and packed by Takgene Pharmaceutical Company, Tehran, Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Neda Dolatkah

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Emam Reza hospital, Golgasht Str., Azadi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Neda Dolatkah
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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