

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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/m<sup>2</sup> 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)

##### Phone

+98 41 3336 1928

##### Email address

dolatkhan@tbzmed.ac.ir

##### 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/m<sup>2</sup>

**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 Dolatkhah

##### **Street address**

Emam Reza hospital, Golgasht Str., Azadi Ave.

##### **City**

تبریز

##### **Province**

East Azarbaijan

##### **Postal code**

5163995479

##### **Phone**

+98 41 3336 1928

##### **Email**

neda\_dolatkhah@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

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

Abolghasem Jouyban

##### **Street address**

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

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6532589875

##### **Phone**

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##### **Email**

research-vice@tbzmed.ac.ir

**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 Dolatkhah  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Nutrition  
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## Person responsible for scientific inquiries

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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