Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of probiotic saccharomyces boulardi on anthropometric indecies, 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 boulardi on anthropometric indecies, 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 Dolatkhah

Name of organization / entity

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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 indecies, 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 Dolatkhah
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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
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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 Dolatkhah
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Nutrition
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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