ISRCTN34652973 https://doi.org/10.1186/ISRCTN34652973

Effects of probiotics supplementation on body mass index, blood sugar control, and lipid levels in individuals with type 2 diabetes mellitus

Submission date
26/12/2023

Recruitment status
No longer recruiting

Registration date
05/01/2024

Overall study status
Completed

Last Edited
30/12/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Probiotics may help manage type 2 diabetes by modifying the intestinal microbiota, which refers to all of the microorganisms that live within the human gut. Several studies have demonstrated a significant association between an individual's gut microbiota and the development of obesity and diabetes. In this study, we investigated the effects of probiotics on body mass index, blood sugar control and lipid profiles (cholesterol and triglyceride levels) in individuals with type 2 diabetes in view of increasing evidence for their role in health and disease.

Who can participate?
Individuals aged 30–75 years with type 2 diabetes for at least 10 months before study initiation and HbA1c level ≥6.5%

What does the study involve?
Eligible individuals were allocated into two equal groups, to receive either probiotic capsules or placebo for 12 weeks. The placebo capsule, which contains 200 mg of starch, was packaged as probiotic capsules and the probiotic and placebo packs were identical in appearance. All participants were instructed to take two capsules orally each day with lunch and not change their routine physical activity or foot.
The individuals' height were measured using a simple tape, whereas body weights were measured using a digital floor scale with minimum clothing. Body mass index, waist circumference and fasting blood samples for assessment of blood sugar control and lipid profile were measured at baseline and after 12 weeks of taking the probiotics capsules.

What are the possible benefits and risks of participating?
Probiotics are generally considered safe. Improvement in blood glucose, cholesterol levels and body mass index were expected after 3 months and this may help to reduce the intensity and the burden of anti-diabetic medications, and by lowering cholesterol levels, might be expected to lower the chance of having cardiovascular incidents. Side effects are generally uncommon, and mainly bowel-related such as diarrhea, constipation, and bloating.

Where is the study run from?
The study was run by Baghdad-Al-Karkh Heath Directorate and took place in the Diabetes Outpatient Clinic of Imamein Kadhimein Medical City and Al-Yarmook Teaching Hospital-National Diabetes Center (Iraq)

When is the study starting and how long is it expected to run for?
June 2021 to June 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Sarah Zalzala, sarahhaider1988@gmail.com
2. Dr Khalid Fahad, Khalid.fahad@nhs.net

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Sarah Hayder Ali Zalzala

ORCID ID
https://orcid.org/0000-0002-5100-9414

Contact details
Medical City Complex
Bab Al-Muaadham
Baghdad
Iraq
61928
+964 (0)7902639659
sarahhaider1988@gmail.com

Type(s)
Public, Scientific

Contact name
Dr Ban Abdul-Ridha Salman Al-Hashimi

Contact details
Medical City
Bab Al-Muaadham
Baghdad
Iraq
61928
+964 (0)7901365134
banhashimi@gmail.com

Type(s)

Public, Scientific

Contact name
Miss Zahraa Hayder Ali Zalzala

Contact details
Ministry of Health
Al-Bakriya Primary Health Care Centre
Baghdad
Iraq
87H6+3W9
+964 (0)7702667675
zazazalzala@yahoo.com

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Khalid Fahad

ORCID ID
https://orcid.org/0000-0002-5767-0203

Contact details
Department of Medicine
Bedford Hospital
South Wing
Kempston Road
Bedford
United Kingdom
MK42 9DJ
+44 (0)7471780109
Khalid.Fahad@nhs.net

Additional identifiers

Protocol serial number
2021034

Study information

Scientific Title
Effects of specific symbiotic supplements on anthropometric measurements, glycaemic control, and lipid profiles among individuals with type 2 diabetes mellitus in two teaching hospitals in Baghdad/Iraq, a double-blind randomized placebo-controlled trial

Study objectives

It is hypothesized that symbiotic supplementation would lead to better management of type 2 diabetes mellitus (T2D) which would be reflected in a decreased HbA1c after 12 weeks of intervention, as well as in anthropometric measures - especially weight, body mass index (BMI) and waist circumference (WC) - and fasting blood samples (FBS) and lipid profiles.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/07/2021, Arabic Board for Health Specializations in Iraq (Bab Al-Muaadham, Baghdad, 61928, Iraq; +964 (0)4140599; info@meciq.edu.iq), ref: 2021034

2. Approved 25/07/2021, Ministry of Health - Baghdad Al-Karkh Health Dirctorate (Kadhimiya District, Baghdad, -, Iraq; +964 (0)5224675; kbhoffice@yahoo.com), ref: 2021034

Primary study design
Interventional

Study design
Double-blind placebo-controlled parallel clinical trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
To ensure allocation concealment and blinding, the placebo and probiotic supplements were identically packaged and the main researcher and participants were blinded to the capsule content throughout the study procedure and final analysis. The probiotic and placebo packs were identical in appearance and differentiated only by the code (A or B) placed on them. Simple randomisation was used for equal allocation to two parallel groups, with odd and even numbers used for allocation. Patients who visited the aforementioned outpatient clinics on interview dates with even numbers received packages labelled A, and vice versa. The allocation ratio was set to 1:1.

This study was conducted among 66 individuals with T2D who were randomly allocated into two groups, comprising 33 individuals each, to receive either Protexin BALANCE capsule symbiotics in the form of 200 million CFUs of L. casei PXN 37, Lactobacillus rhamnosus PXN 54, S. thermophilus PXN66, L. acidophilus PXN 35, B. breve PXN 30, B. longum PXN 30, and Lactobacillus bulgaricus PXN 39 plus fructooligosaccharide (FOS) daily dose (n=33) or placebo (n=33) for 12 weeks. The ADA recommends that the HbA1c and lipid profiles of patients be measured every 3 months to assess whether glycaemic targets have been reached and/or maintained; therefore, we selected 12 weeks to observe the effect of the intervention on the variables.

The placebo was prepared locally with the help of a pharmacist by adding approximately 200 mg of starch to empty capsules, which were subsequently sealed and packaged as probiotic capsules. All participants were instructed to take two capsules orally each day with lunch and not alter their routine physical activity or diet.

The patients' heights were measured using a non-stretchable tape, with 0.1 cm accuracy, whereas body weights were measured using a digital floor scale without shoes and with minimum clothing. BMI, determined by dividing body weight by the square of height (kg/m2), and WC were assessed at baseline and after 12 weeks of intervention.
Fasting blood samples (FBS, high-density lipoprotein [HDL], low-density lipoprotein [LDL], total cholesterol [TC], serum triglycerides [TG] and HbA1c) were collected at baseline and after 12 weeks of intervention.

Compliance was assessed through weekly (or more frequently, if required) phone interviews, and patients were asked about any side effects. Face-to-face interviews were conducted at the end of 12 weeks, and patients were instructed to bring their capsule packages to be counted.

Intervention Type
Supplement

Primary outcome(s)
HbA1C is measured by venous blood sample at baseline and 12 weeks

Key secondary outcome(s)
Assessed at baseline and 12 weeks:
1. BMI determined by dividing body weight by the square of height (kg/m2)
2. Waist circumference measured using a non-stretchable tape with 0.1-cm accuracy
3. Fasting blood sugar measured using a fasting venous blood sample
4. Lipid profiles measured using a fasting venous blood sample

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Individuals with T2D according to the criteria of the American Diabetes Association (ADA) for at least 10 months prior to study initiation
2. Individuals aged 30–75 years
3. Individuals with an HbA1c level ≥6.5%
4. Individuals able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
61

Key exclusion criteria
1. Individuals who were current smokers
2. Individuals with immunocompromised conditions
3. Individuals with diabetes controlled by insulin
4. Individuals who were pregnant or breastfeeding
5. Individuals with inflammatory bowel disease; pancreatitis; chronic kidney, hepatic, or pulmonary diseases; severe anaemia; or cancer
6. Individuals using nutritional supplements, laxatives, or nonsteroidal anti-inflammatory drugs in the past 3 weeks
7. Individuals using antibiotics within the past 3 months prior to study initiation

Date of first enrolment
01/09/2021

Date of final enrolment
03/04/2022

Locations

Countries of recruitment
Iraq

Study participating centre
Imamein Kadhimein Medical City
Al-Kadhmiya
Baghdad
Iraq
14222

Study participating centre
Al-Yarmook Teaching Hospital
Al-Yarmook District
Baghdad
Iraq
N/A

Sponsor information

Organisation
Arab Board of Health Specializations in IRAQ

Organisation
Ministry of Health - Baghdad Al-Karkh Health Dirctorate

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request (Dr Sarah Zalzala, sarahhaider1988@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/12/2024	30/12/2024	Yes	No