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Effect of dietary supplements on type 2 diabetes

Submission date
21/10/2022

Recruitment status
No longer recruiting

Registration date
09/11/2022

Overall study status
Completed

Last Edited
11/07/2023

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
Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by high blood sugar, insulin resistance and chronic inflammation. Several studies have reported gut microbiome dysbiosis (gut bacteria disruption) as a factor in the rapid progression of insulin resistance in T2DM. Probiotic-containing formulations have been reported as useful in the management of T2DM. BiotiQuest™ Sugar Shift (SS) is a symbiotic formulation rationally designed for the conversion of glucose and fructose to support the restoration of the human gut microbiota, the modulation of intestinal glucose, and the production of anti-inflammatory metabolites and therefore to help stabilize blood glucose, improve insulin resistance, and reduce inflammation. The aim of this study is to evaluate the effectiveness of SS at reducing T2DM biomarkers, blood sugar, HbA1c, insulin levels, insulin resistance and inflammation.

Who can participate?
Patients diagnosed with T2DM, between 30 and 65 years old, with body mass index (BMI) between 28-40 kg/m² at the enrollment visit, who attended the diabetes-specialized consultations of the Hermanos Ameijeiras Hospital

What does the study involve?
Patients are randomly allocated to consume SS or placebo daily, two capsules per day, 12 hours apart. Patients visit the clinic for evaluation, sample collection and administration of capsules four times during the 12-week study. The variables measured during each visit are age, sex, BMI, blood pressure, and history of COVID-19 infection. Fecal samples are collected at the beginning and the end of the study, and blood samples are collected during each visit to the clinic.

What are the possible benefits and risks of participating?
All patients receive the standard of care and private consultations with the attending physician. Benefits to the patient include monthly health monitoring and nutritional clinical counseling as well as guidance for a healthy daily routine.

Where is the study run from?
Hospital Hermanos Ameijeiras (Cuba)

When is the study starting and how long is it expected to run for?
May 2020 to October 2022

Who is funding the study?
The BioCollective, LLC, (USA)

Who is the main contact?
1. Martha R. Carlin
2. Raul J. Cano, rcano@calpoly.edu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HHA_CCF_000030

Study information

Scientific Title
Clinical study on the effect of BiotiQuest™ Sugar Shift and Kesto Mix dietary supplements on the treatment of type 2 diabetes mellitus

Acronym

SST2DM

Study objectives
Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by hyperglycemia, insulin resistance and chronic inflammation. Several studies have reported gut microbiome dysbiosis as a factor in the rapid progression of insulin resistance in T2DM which accounts for about 90% of all diabetes cases worldwide. Probiotics, prebiotics, symbiotics, and postbiotics benefit metabolic disease management, especially obesity and type 2 diabetes mellitus. BiotiQuest™ Sugar Shift (SS) is a symbiotic formulation rationally designed for the conversion of glucose and fructose to support the restoration of the human gut microbiota, the modulation of intestinal glucose, and the production of anti-inflammatory metabolites and therefore stabilize blood glucose, improve insulin resistance, and reduce inflammation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/06/2021, Comité de Ética de la Investigación Científica (Ethics Committee For Scientific Investigation, Hospital Clínico Quirúrgico Hermanos Ameijeiras, San Lázaro 701 esq. Belascoain, Centro Habana, CP 10300. La Habana, Cuba; +53 (0) 78761000; hha@infomed.sld.cu), ref: not provided

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://www.dropbox.com/s/xvepy236cwhxs88/CONSENTIMIENTO%20INFORMADO%20PARAPARTICIPAR%20EN%20EL%20ESTUDIO%20CL%C3%96NICO%20EFICACIA%20DE%20BIOTIQUEST.doc?dl=0

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

Interventions
The included patients are assigned to two treatment groups by randomization:
Group A (study or experimental): Sugar Shift (SS)
Group B (control): placebo

Assignment to treatment groups is carried out using epidemiological analysis from tabulated data. Participants consume SS or placebo daily, two capsules per day, 12 hours apart. Patients visit the clinic for evaluation, sample collection and administration of capsules four times during the 12-week study. The foil packaging containing the capsules is distributed every 28 days over the 12-week study period after blood sample collection for clinical determination. The “test substance”, SS, is manufactured by BlisterPak Pro, LLC in Lafayette, Colorado™. Each capsule contains 96 mg (18 billion CFU) of a bacterial consortium of eight strains of GRAS-classified bacteria that include Bacillus subtilis de111™, Bifidobacterium bifidum, Bifidobacterium longum, Lactobacillus paracasei, Lactobacillus plantarum TBC0036, Lactobacillus reuteri, Leuconostoc mesenteroides TBC0037, and Pediococcus acidilactici. Each capsule contains 370 mg of prebiotics and fillers consisting of inulin, microcrystalline cellulose, D-mannitol, and stearic acid. The placebo capsules were manufactured by BlisterPak Pro, LLC in Lafayette, Colorado™. Each capsule contains 370 mg of prebiotics and fillers consisting of inulin, microcrystalline cellulose, D-mannitol, and stearic acid.

Intervention Type
Supplement

Primary outcome measure
Hemoglobin A1c (Hb-A1c) (%) determined in K3EDTA blood collection tubes at the beginning of the study (Day 1) and the last day (Day 84)

Secondary outcome measures
1. Fasting blood glucose (FBG) determined in serum samples every 28 days (day 1, day 28, day 56 and day 84)
2. Postprandial glucose (2 hours) determined in serum samples every 28 days (day 1, day 28, day 56 and day 84)
3. Cholesterol determined in serum samples at the beginning of the study (Day 1) and the last day (Day 84)
4. Triglycerides determined in serum samples at the beginning of the study (Day 1) and the last day (Day 84)
5. HDLc determined in serum samples at the beginning of the study (Day 1) and the last day (Day 84)
6. LDLc determined in serum samples at the beginning of the study (Day 1) and the last day (Day 84)
7. Insulin determined in serum samples at the beginning of the study (Day 1) and the last day (Day 84)
8. Creatinine determined in serum samples at the beginning of the study (Day 1) and the last day (Day 84)
9. LPS: Endotoxin units / mL determined in serum samples at the beginning of the study (Day 1) and the last day (Day 84)
10. Microbiome analysis: 16S amplicon sequencing determined in fecal samples at the beginning of the study (Day 1) and the last day (Day 84)

Overall study start date
17/05/2020

Completion date
07/10/2022

Eligibility

Key inclusion criteria
1. Patients diagnosed with T2DM
2. Between 30 and 65 years old
3. Body mass index (BMI) between 28-40 kg/m² at baseline
4. Attended the diabetes specialized consultations of the Hermanos Ameijeiras Hospital
5. Gave their consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The sample size was estimated with a two-sided alpha of 0.05, 95% confidence level, standardized mean difference of 0.75, test power of 80%, expected proportion of losses of 10%. Based on this information, the minimum required sample size was estimated to be 28 individuals per group; adjusted for losses for various reasons, the sample size was established at 32.

Total final enrolment
64

Key exclusion criteria
1. Chronic kidney disease
2. Onco-proliferative diseases
3. Pregnant women

Date of first enrolment
01/08/2022

Date of final enrolment
04/08/2022

Locations

Countries of recruitment
Cuba

Study participating centre
Hospital Clínico Quirúrgico Hermanos Ameijeiras
Calle, # 701 San Lazaro

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Sponsor information

Organisation
The BioCollective, LLC

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
The BioCollective, LLC

Results and Publications

Publication and dissemination plan
A manuscript summarizing the results of the study is in preparation and nearly ready for submission to PLoS ONE. Presentations in the form of abstracts or talks will also be presented at pertinent scientific meetings

Intention to publish date
01/07/2023

Individual participant data (IPD) sharing plan

The anonymised datasets generated during and/or analysed during the current study will be available upon request from Raul J. Cano, PhD (rcano@calpoly.edu). A portion of these data will be made available as supplementary material in a forthcoming publication

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/06/2023	11/07/2023	Yes	No