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Evaluation of a food supplement (Opunxia™) in improving intestinal health

Submission date	Recruitment status	[X] Prospectively registered
02/05/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/05/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/04/2024	Digestive System	

Plain English summary of protocol

Background and study aims
An imbalance in intestinal bacteria (gut dysbiosis) can lead to damage to the intestine. Intestinal permeability is a factor related to several health problems like inflammation, allergy, and immunity. The supplement Opunxia can form a physical protective layer on the intestinal lining. The aim of this study is to demonstrate that Opunxia has a benefit on overall health by improving the intestinal bacteria in general and some strains involved in immunity, cognition, oxidation and inflammation.

Who can participate?
Patients aged 25 to 50 years with gut dysbiosis

What does the study involve?
Participants are asked to attend clinic visits at screening and after 4 and 8 weeks of Opunxia intake. During the screening visit, the medical doctor informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects fix then the date for the first visit. Participants are asked to collect a stool sample the day before the first visit. During the first visit the subject gives a stool sample to the study staff, the medical doctor evaluates them with questionnaires and their body mass index (BMI), weight, hip and waist circumferences are measured. The participants are then randomly allocated to use the Opunxia™ food supplement or the placebo (dummy) product for 8 weeks. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 8 weeks with an intermediate check at 4 weeks.

What are the possible benefits and risks of participating?
The potential benefit of participating is an improvement of overall health by improvement of the gut microbiome. All the ingredients included in the product are approved for their use in food supplements and are used at the permitted concentration. The potential risks associated with the use of the product are assumed to be mild to moderate and are not expected to pose a risk to health. Risks associated with the procedures involved in this study are judged as minor.

All precautions will be taken to ensure that the risk is the lowest possible. All the measurements carried out are minimally invasive and no side effects are expected from the measurement process.

Where is the study run from?
Nutratech srl spin-off Università della Calabria (Italy)

When is the study starting and how long is it expected to run for?
January 2022 to March 2023

Who is funding the study?
BIONAP srl (Italy)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
H.E.HU.MP.NMA00.080.05.00_ IT0002109/22

Study information

Scientific Title
Opunxia clinical trial. Effect of Opunxia™ supplementation on overall health through an improvement of the intestinal microbiome in subjects with dysbiosis

Acronym
OCT_M&D

Study objectives
The trial is aimed to evaluate the efficacy of Opunxia™ on the overall health through an improvement of the intestinal flora in subjects with intestinal dysbiosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2022, Comitato Etico Di Ateneo (CEA) Università della Calabria (Via Pietro Bucci Cubo 15/D - 87036 Arcavacata di Rende (CS), Italy; +39 (0)984 496940; cea@unical.it), ref: not applicable

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gut dysbiosis

Interventions
The active intervention (Opunxia™) is a highly concentrated extract of Opuntia Ficus Indica cladodes containing a high amount of cladode polysaccharides; while the placebo intervention is maltodextrin. Both the active and the placebo products are used as follows: one capsule per day intake after lunch or after dinner. Half of the test subjects will be randomized to receive the test product and half of the test subjects will be randomized to receive the placebo product. A restricted randomization list will be created using PASS 2008 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place. The randomization sequence will be stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence will be concealed from the in-site study director in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on the subject entry

number in the study). The A4 sheet reporting the unblinded treatment will be folded to render the envelope impermeable to intense light. A masked allocation sequence will be prepared for the staff delivering the intervention based on the subject entry number in the study.

Participants are asked to attend clinic visits at screening and after 4 and 8 weeks of Opunxia intake. During the screening visit, the medical doctor informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the subjects fix then the date for the first visit. Participants are asked to collect a stool sample the day before the first visit. During the first visit the subject gives a stool sample to the study staff, the medical doctor evaluates them with questionnaires and their body mass index (BMI), weight, hip and waist circumferences are measured. The participants are then randomly allocated to use the Opunxia™ food supplement or the placebo (dummy) product for 8 weeks. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 8 weeks with an intermediate check at 4 weeks.

Intervention Type
Supplement

Primary outcome(s)
Intestinal flora evaluated by microbiome analysis using 16S rRNA gene sequencing at screening and after 4 and 8 weeks

Key secondary outcome(s)
1. Weight and BMI management and control measured by a balance and a meter at screening and after 4 and 8 weeks
2. Intestinal permeability measured using zonulin levels in faeces at screening and after 4 and 8 weeks
3. Gastrointestinal health measured using the GERD Symptom Assessment Scale (GSAS) and Gastrointestinal Quality of Life Index (GIQLI) validated questionnaires at screening and after 4 and 8 weeks
4. Hip and waist measurement using a flexible meter at screening and after 4 and 8 weeks

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Healthy subjects aged 25-50 years
2. Reading, understanding and signing approval of the informed consent
3. Computer literate and exposed to computerized tests
4. Available and willing to follow the procedure of the study protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
1. Subjects <25 and >50 years old
2. Clinical history with the relevant presence of any disorder or administration of drugs/food supplement that can potentially interfere with the treatment under study
3. Consumption of any drugs or food supplements that can interfere with intestinal activity
4. Smokers
5. Lack of compliance (defined as not using the correct Opuntia™ dose or placebo for>1 week), and inability to give informed consent
6. BMI ≥30 kg/m²
7. Pregnant and lactating women
8. Excessive alcohol consumption (>5 drinks/week)
9. Subjects with a history of drug, alcohol, and other substance abuse
10. Known food intolerance or food allergy
11. Subjects involved in a clinical or food study within the previous month
12. Subjects who have unstable medical diseases (cardiac arrhythmias or ischemia, uncontrolled hypertension, hypotension, diabetes mellitus, kidney failure)
13. Subjects with a history of paralysis or cerebral vascular accident
14. Subjects with active cancers or on chemotherapy
15. Other factors that limit their ability to cooperate during the study

Date of first enrolment
10/05/2022

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Italy

Study participating centre
Nutratech srl spin-off Università della Calabria
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Sponsor information

Organisation

BIONAP srl

Funder(s)

Funder type
Industry

Funder Name
BIONAP srl

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored on Complife servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer's management software. The code is composed of a letter, four digits, and a letter. Access to the study raw data is allowed only to the study director and the person designated by him to elaborate on the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and inferential analysis (data normality and statistical test).

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/02/2024	17/04/2024	Yes	No