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Complex dietary supplement (cocktail) for healthy longevity

Submission date
31/01/2025

Recruitment status
No longer recruiting

Registration date
04/02/2025

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This research project investigates a natural supplement blend, including prebiotics, autophagy stimulators, senolytic activators, and natural probiotics found in vegetables and fruits. The study aims to explore the effects of this supplement, known as CoLoSaN, on biomarkers that assess healthy longevity in medically healthy individuals. By examining these effects, the study seeks to provide insights into how such a supplement can contribute to a longer, healthier life.

Who can participate?
Healthy adult volunteers

What does the study involve?
The present clinical study involves the oral administration of five nutritional supplements: organic boron, calcium butyrate, iron chelators (curcumin and epigallocatechin), autophagy stimulators and senolytic activators (spermidine, glutamine, fisetin, and quercetin), and a probiotic complex (Lactobacillus plantarum, Streptococcus thermophilus, Bifidobacterium animalis, B. adolescentis, B. longum, Bacillus subtilis, and Bacillus coagulans). Each supplement is taken once daily, either after breakfast or lunch, for 60 days. Participation in this study is entirely voluntary, with an equal gender ratio among participants. This single-center study is conducted at the Bioboron Institute Craiova-Podari. Blood tests are collected at the beginning and end of the study to assess the effects of the supplements.

What are the possible benefits and risks of participants?
The immediate effect on patients is beneficial in that inflammatory and lipid markers are expected to decrease significantly. In the long term, the quality of life of the subjects involved in the study is expected to improve significantly.

The supplements have no known adverse effects. All the ingredients in the supplement cocktail are natural or identically natural, and each has been through toxicity testing showing that long-term supplementation has posed no health risks.

Where is the study run from?
The Bioboron Institute Craiova -Podari

When is the study starting and how long is it expected to run for?
January 2025 to March 2025

Who is funding the study?
1. The Bioboron Institute
2. The University of Medicine and Pharmacy Craiova

Who is the main contact?
Prof Dr Romulus Ion Scorei, romulus.scorei@naturalresearch.ro, romulus_ion@yahoo.com

Study website
https://www.naturalresearch.ro/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Microbiota-accessible cocktail for healthy longevity

Acronym
CoLoSaN

Study objectives
This "Complex Dietary Supplement (cocktail) for Healthy Longevity" (CoLoSan) cocktail targets biomarkers proven to be involved in the prognosis of a long and healthy life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/01/2025, Bioethic Board of Natural Research, Bioboron Research Institute in Craiova (Dunarii street No,31, Podari, 207465, Romania; +40351 433 500 int. 4031; cosmin.cristea@umfcv.ro), ref: No.7/10.01.2025

Study design
Single-centre randomized controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Healthy adults

Interventions
The present clinical study involves the oral administration of the following 5 nutritional supplements:
1. Organic boron (1 capsule per day);
2. Calcium butyrate (1 capsule per day);
3. Iron chelators (curcumin and epigallocatechin) (1 capsule per day);
4. Autophagy stimulators and the senolytic activators (spermidine, glutamine, fisetin and quercetin) (1 capsule per day);
5. Probiotic Complex (Lactobacillus plantarum, Streptococcus thermophilus, Bifidobacterium animalis, B.adolescentis, B.longum, Bacillus subtilis and Bacillus cuagulans). (1 capsule per day);
The supplements will be taken during the same day, after breakfast and/or lunch (once or twice) for 60 days.

Participation in this research is entirely voluntary with a 1:1 gender ratio selection. Procedures and Protocol
This clinical trial is single-center, randomized and controlled. The trial site is the Bioboron Institute Craiova -Podari. Blood tests will be collected once at the beginning of the study and a second time at the end of the study (after 60 days).

Intervention Type
Supplement

Primary outcome measure
1. Stool quality and significant general symptoms associated with intestinal dysmotility measured using questionnaires [is this a named tool, or bespoke?] at [timepoint]
Stool quality and significant general symptoms associated with intestinal dysmotility measured using (VAS-IBS) self-estimation on gastrointestinal symptoms - questionnaire, at 30 days and 60 days

2. Levels of uric acid, high sensitivity C-reactive protein (hs-CRP), creatinine, lipid profiles (high-density lipoprotein-C [HDL-C], low-density lipoprotein-C [LDL-C], total cholesterol [TC], triglycerides [TGs]), liver enzymes (gamma-glutamyl transferase [GGT], alkaline phosphatase [ALP], and lactate dehydrogenase [LDH]), glucose, total iron and total iron-binding capacity (TIBC) measured using blood tests at baseline and 60 days

2. Biochemical parameters were measured using standardized methods on an Alinity c analyzer and, for ferritin, on a Cobas 6000 platform:
2.1. Levels of uric acid: a spectrophotometric method dedicated to the quantitative detection of uric acid in clinical specimens; reference values: 2.5-6.2 mg/dL for women and 3.7-7.7 mg/dL for men.
2.2. High sensitivity C-reactive protein (hs-CRP): CRP Vario Reagent kit – quantitative immunoturbidimetric determination of C-reactive protein with variable assay ranges: CRP48 and CRP16 (high sensitivity CRP method); reference values: 0-5 mg/L for CRP < 1mg/L for hs-CRP
2.3. Creatinine: a spectrophotometric method dedicated to the quantitation of creatinine in clinical specimens (serum, plasma, urine); reference values: 0.55-1.02 mg/dL for women 0.73-1.18 mg/dL for men
2.4 Lipid profiles (high-density lipoprotein-C [HDL-C], low-density lipoprotein-C [LDL-C], total cholesterol [TC], triglycerides [TGs]):
2.4.1. High-density lipoprotein-C [HDL-C]: Ultra HDL assay - a homogeneous method for directly measuring HDL- cholesterol in serum or plasma without the need for off-line pretreatment or centrifugation steps accomplished using finally a spectrophotometric method; reference values: 55-100 mg/dL for women and 50-100 mg/dL for men
2.4.2. Low-density lipoprotein-C [LDL-C]: calculated using the Friedewald formula: LDL-cholesterol = Total Cholesterol – (HDL-cholesterol + VLDL-cholesterol); reference values: 60-100 mg/dL
2.4.3. Total Cholesterol (TC): a spectrophotometric method dedicated to the quantitation of cholesterol in serum or plasma; reference values: 70-240 mg/dL
2.4.4. Triglycerides [TGs]: a spectrophotometric method dedicated to the quantitation of triglycerides in serum or plasma; reference values: <150 mg/dL
2.5.1. Liver enzymes (gamma-glutamyl transferase [GGT], alkaline phosphatase [ALP], and lactate dehydrogenase [LDH]):
2.5.2. Gamma-glutamyl transferase (GGT) - a spectrophotometric method dedicated to the quantitation of GGT activity in serum or plasma: reference values: 0-38 U/L for women 0-55 U/L

for men
2.5.3. Alkaline Phosphatase (AlP) – a spectrophotometric method dedicated to the quantitation of AlkP activity in serum or plasma: Reference values: 46-122 U/L for women and 50-116 U/L for men;
2.5.4. Lactate dehydrogenase (LDH) - a spectrophotometric UV method dedicated to the quantitation of LDH activity in serum or plasma; reference values: 125-220 U/L;
2.6. Glucose: a spectrophotometric method dedicated to the quantitation of glucose in biological fluids; reference values: 70-110 mg/dL
g) total iron and total iron-binding capacity (TIBC) measured using blood tests at baseline and 60 days:
2.7. Iron - a spectrophotometric method dedicated to the quantitation of iron in serum or plasma; reference values: 50-170 µg/dL for women and 65-175 µg/dL for men
2.8. Transferrin - an immunoturbidimetric method dedicated to the quantitation of transferrin in serum or plasma; reference values: 180-382 mg/dL for women and 174-364 mg/dL for men
2.9. Ferritin – a chemiluminescence method for the quantitative determination of ferritin in human serum and plasma; reference values: 13-150 ng/mL for women; 30-400 ng/mL for men
2.10. Total Iron Binding Capacity of Transferrin (TIBC) was calculated as follows: TIBC (µmoles/L) = Transferrin (g/L) x 25.2

Secondary outcome measures
The following secondary outcome measures are assessed at 60 days:
1. Adverse events, defined using the Romanian Medicines Agency Guidelines, measured using data collected from the patient card
for spontaneous reporting of adverse drug reactions
2. Quality of life measured using the World Health Organization Quality of Life (WHOQOL) brief short-form assessment

Overall study start date
01/01/2025

Completion date
05/03/2025

Eligibility

Key inclusion criteria
1. Clinically healthy subjects
2. Male or female patients
3. Age >40 years
4. BMI range 17-27 kg/m2 (normal, overweight, but not obese)
5. Normal or minor hypertension <140/80-90 mmHg
6. Informed consent was obtained at screening

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
40 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
13

Total final enrolment
12

Key exclusion criteria
1. Refusal to participate or to sign informed consent
2. Proven co-infection with Clostridium difficile
3. Other infections except for respiratory tract
4. Known IBD or other diseases that may significantly influence MG

Date of first enrolment
05/01/2025

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Romania

Study participating centre
University of Medicine and Pharamcy in Craiova
Petru Rares Street No.2, Craiova
Craiova
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Sponsor information

Organisation
Natural Research Bioboron Research Institute

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Sponsor type
Research organisation

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Sponsor type
University/education

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ROR
https://ror.org/031d5vw30

Funder(s)

Funder type
Industry

Funder Name
Natural Research Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
07/10/2025

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in a non-publicly available repository at https:// www.naturalreseach.ro/ and will be published as a supplement to the publication of the results.

This proposal has been reviewed and approved by the Institutional Ethics Committee of the University of Medicine and Pharmacy of Craiova, Romania, to protect all participants in a research study. This trial is in accordance with the 1975 Declaration of Helsinki, which was revised in 2008. This trial has also been reviewed by its sponsors, namely S.C. Natural Research S. R.L. Craiova and the University of Medicine and Pharmacy of Craiova, Dolj, Romania

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			04/02/2025	No	No
Participant information sheet		08/12/2024	04/02/2025	No	Yes