

Complex dietary supplement (cocktail) for healthy longevity

Submission date 31/01/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/02/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/02/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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: $TIBC (\mu\text{moles/L}) = \text{Transferrin (g/L)} \times 25.2$

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

40 years

Upper age limit

80 years

Sex

All

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 Pharmacy in Craiova

Petru Rares Street No.2, Craiova

Craiova

Romania

200349

Sponsor information

Organisation

Natural Research Bioboron Research Institute

Organisation

University of Medicine and Pharmacy of Craiova

ROR

<https://ror.org/031d5vw30>

Funder(s)

Funder type

Industry

Funder Name

Natural Research Ltd

Results and Publications

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.naturalresearch.ro/](https://www.naturalresearch.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
Study website	Study website	11/11/2025	11/11/2025	No	Yes