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A study to evaluate the effects of the combination of GI-102 with GIB-7 on biomarkers of aging in healthy adults and cancer survivors

Submission date
10/12/2025

Recruitment status
No longer recruiting

Registration date
09/01/2026

Overall study status
Completed

Last Edited
20/05/2026

Condition category
Other

[X] 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
Aging involves a decline in cognitive function (mental abilities, including memory, thinking, and reasoning skills), muscle mass and the body's immune system (the system responsible for defending the body against threats like infection and cancer), among other things. Although lifestyle choices such as physical exercise and a good diet provide some benefit, there are limits to their anti-aging effect.

The main purpose of the study is to see if two experimental drugs, GI-102 and GIB-7, affect aging by looking at changes in your immune system, sleep quality, physical activity, muscle function, general health and wellbeing, cognition (mental abilities, including memory, thinking, and reasoning skills), gut microbiome (the bacteria in the gut), and blood testing to see how fast your body is aging.

GI Innovation Inc. and GI Longevity Inc. are developing the study drugs, GI-102 and GIB-7, respectively, to be used as a potential new combined treatment for aging. Each drug will act differently, which is expected to have an overall anti-aging effect.

As we get older, our immune system begins to decline in activity and function. GI-102 is designed to boost the body's immune system by targeting a specific type of immune cell and increasing molecules called cytokines (proteins that act as messengers in the immune system). Cytokines help to control inflammation, which is your body's response to potentially harmful things like disease, cell damage, and irritants, and is shown by signs like heat, pain, swelling, and redness. This is expected to help drive and restore crucial parts of the immune system that decline with aging.

The healthy bacteria in our body's gut are important to how we digest food and obtain nutrients, but they also play an important role in our immune system's function, including how our body controls inflammation. GIB-7 contains a mix of probiotics (healthy bacteria) and prebiotics (things like vitamins that help the healthy bacteria grow). It is expected that GIB-7 will enhance the healthy bacteria in the gut and enhance our body's digestion and immune system regulation.

GIB-7 has been tested in humans before in a study of elderly adults in South Korea, which showed improvements in mood, sleep and gut function. GIB-7 is still under development and has not been approved as a drug by any government authority in any country. However, it has received health functional food certification in Korea and is sold under the name of 'Number Seven' in South Korea.

Who can participate?
People who are aged between ≥18 and ≤80 years old in a state of general health or cancer survivors.

What does the study involve?
The study will involve administration of GI-102, given once a month via infusion for eight weeks, and GIB-7, taken orally every day for eight weeks in the main period. Blood samples will be collected to assess changes in immune function. Participants will also complete validated questionnaires to evaluate their overall well-being and muscle function tests. In addition, cognitive assessments will be conducted using questionnaires and an iPad-based tool (NIH Toolbox). It will take 8 weeks in the main period. This study has an optional extension period (3-Months Treatment + 2 Weeks Follow-up) to ensure continuity of care for the participants who respond well to the combination treatment and must be willing to continue in the study.

What are the possible benefits and risks of participating?
There is no direct medical benefit to participants for taking part in this study, and it is unlikely to improve long-term health. However, participation will help gain scientific knowledge that may contribute to the development of new treatments for others in the future. While the study is carefully monitored, participants may experience unwanted or unexpected side effects from the treatment. Participants will be monitored by the research team at every visit. Since the effects of this treatment on pregnancy are not yet known, anyone who is pregnant or breastfeeding is excluded from the study. Participants are also asked to use effective contraception throughout the trial.

Where is the study run from?
1. Novatrials (Australia), Southern Oncology Clinical Research Unit (Australia)
2. Samsung Medical Center (South Korea)

When is the study starting and how long is it expected to run for?
Recruitment begins in January 2026 for 4 months until May 2026. The study ends in October 2026.

Who is funding the study?
GI Innovation, Inc. (co-funded by GI Longevity, Inc.)

Who is the main contact?
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Study information

Scientific Title
Phase 2a, proof-of-concept, multi-national, 8-week, randomized, single-blinded, placebo-controlled trial of GI-102 in combination with GIB-7 to evaluate its effects on biomarkers of aging in healthy adults and cancer survivors

Acronym
GIANTS-1

Study objectives
This phase 2a clinical study (GIANTS-1) aims to evaluate a novel dual combination strategy using GI-102 and GIB-7 to address key pathological features of aging, including immunosenescence (the aging of the immune system), metabolic dysfunction, and gut-brain-muscle axis dysregulation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/11/2025, Bellberry Human Research Ethics Committee (Level 1, 196 Greenhill Road, Eastwood, Adelaide, 5063, Australia; +61 8 8361 3222; bellberry@bellberry.com.au), ref: 2025-09-1553

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Cancer Survivors, Healthy Participant, Elderly

Interventions
The dose of randomisation is 0.02 mg/kg of GI-102. The method of randomisation is centralized, stratified randomization (stratification based on geographic location; Australia versus South Korea). Site staff will be notified of the participant's group assignment on Day 1.

1) Active Comparator: Part A
- GI-102 in combination with GIB-7
- Combination Product: GI-102 in combination with GIB-7
*GI-102: recombinant protein drug, intravenous (IV) infusion, once every 4 weeks (Q4W);
* GIB-7: synbiotic formula, oral administration, once daily (QD)
Other Names:
• efzilonkofusp alfa in combination with GIB-7

2) Active Comparator: Part B Arm 1
- GI-102 in combination with GIB-7
- Combination Product: GI-102 in combination with GIB-7
* GI-102: recombinant protein drug, intravenous (IV) infusion, once every 4 weeks (Q4W);
* GIB-7: synbiotic formula, oral administration, once daily (QD)
Other Names:
• efzilonkofusp alfa in combination with GIB-7

3) Placebo Comparator: Part B Arm 2
- Placebo for GI-102 (normal saline) in combination with GIB-7
* Combination Product: Placebo
* Placebo for GI-102 in combination with GIB-7

Intervention Type
Mixed

Primary outcome(s)
1. Assess immune function through natural killer (NK) cell count and CD8# T cell count measured using flow cytometry in blood samples at baseline, weeks 1, 4, 5, 6 and 10

2. Safety and tolerability of the combination of GI-102 and GIB-7 measured using data collected from electronic Case Report Forms (eCRF) on the frequency of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) by severity, vital signs, electrocardiograms (ECGs), physical examination, chest X-ray, laboratory parameters at baseline, weeks 1, 4, 5, 6 and 10

Key secondary outcome(s)
1. Sleep quality and quality of life measured using the Insomnia severity index (ISI), Center for epidemiologic studies depression scale (CES-D), and EuroQol 5-Dimension (EQ-5D) at baseline and weeks 8 and 10

2. Muscle function measured using handgrip strength test, 6-Minute Walk Test, knee extensor power test, and Bioelectrical Impedance Analysis (BIA) at baseline and weeks 8 and 10

Completion date

01/10/2026

Eligibility

Key inclusion criteria
1. Must be aged between ≥18 and ≤80 years old at the time of informed consent
2. At the discretion of the Investigator, must be in a state of general health that is not severely compromised (ie, no life-threatening illness or disability)
3. Participants with a history of cancer may be included only if they meet one of the following:
3.1. They have been disease-free for ≥2 years; OR
3.2. For those diagnosed within 2 years:
3.2.1. The cancer was treated with curative intent (eg, surgery, anti-cancer agents, including chemotherapy)
3.2.2. They have been in remission for ≥12 months
3.2.3. They are not on any active cancer treatment except maintenance therapies (eg, endocrine therapy or bisphosphonates)
3.2.4. They must have received systemic anti-cancer therapies without immunotherapy for their cancers
4. Women of childbearing potential (WOCBP) must agree to use a highly effective method of contraception from 14 days prior to Visit 2 until 180 days after the last dose of study medication (GI-102 or GIB-7). Fertile men must agree to use an acceptable method of contraception from 14 days prior to Visit 2 until 90 days after the last dose of study medication (GI-102 or GIB-7).

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Severe and poorly managed chronic diseases, such as advanced cardiovascular disease, kidney failure requiring transplant or dialysis, uncontrolled diabetes, detectable malignancy (≤ 2 years), severe chronic obstructive pulmonary disease (COPD), or untreatable, terminal cancer as judged by the Investigator or history of life-threatening infection (eg, meningitis).
2. Dependent on walkers or wheelchairs; severe difficulty or inability to perform activities of daily living independently or inability to perform study measures required to test muscle function (an amputee is eligible if they can walk without walkers or wheelchairs) as judged by the Investigator.

3. Major surgery within the past 6 months or scheduled during the study period, including severe orthopedic diseases requiring joint replacement surgery.
4. History of substance abuse or dependency or history of recreational IV drug use over the last 5 years (by self-declaration).
5. Female participants who are pregnant, planning to become pregnant, or breastfeeding during the study period. Participants undergoing perimenopause or the menopause transition are eligible.

Date of first enrolment
27/01/2026

Date of final enrolment
01/09/2026

Locations

Countries of recruitment
Australia

Korea, South

Sponsor information

Organisation
GI Innovation, Inc.

Funder(s)

Funder type

Funder Name
GI Innovation, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date