A Dose Ranging Target Engagement Study of a Food-Grade Pectic Food Supplement (G3P-01) in Volunteers with Elevated Levels of Galectin-3 - the Galaxy study

Published: 05-04-2023
Last updated: 25-03-2025

Primary Objectives:1. To evaluate target engagement attributable to G3P-01 use in volunteers with elevated galectin-3 (>= 16.0ng/mL)2. To evaluate tolerability of G3P-01Secondary Objectives:1. To provide samples for research and development of...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53335

Source
ToetsingOnline

Brief title
G3P-01 in Volunteers with Elevated Galectin-3 - Galaxy study

Condition

- Other condition

Synonym
Target engagement, tolerability

Health condition

Target engagement, tolerability

Research involving
Human

Sponsors and support

Primary sponsor: General Practitioners Research Institute
Source(s) of monetary or material Support: G3P, Inc.,G3P;Inc.

Intervention

Keyword: Food supplement, galectin-3, Pectin, Target engagement

Outcome measures

Primary outcome

Evidence of target engagement:

1. Evidence of galectin-3 target engagement based on statistical change from

baseline of pathway markers consistent with galectin-3 inhibition

2. Indication of dose-response effect on pathway markers

Tolerability of G3P-01:

1. Changes in the gastrointestinal symptom rating scale (GSRS)

2. Emerging signs or symptoms

3. Laboratory safety parameters (change from baseline or emergence of

clinically significant abnormal values)

Secondary outcome

1. To provide samples for research and development of analytical methods:

- To characterize G3P-01 and its effects on the human body

- For other exploratory scientific purpose related to the effects of

galectin-3 on the body.

Study description

Background summary

G3P-01 is an investigational pectin extracted, enriched and purified from commercial squash puree intended for human consumption. Pectins are an important constituent of fruits and vegetables, and health benefits are attributed to its intake. Some of the health benefits of pectins are attributed to inhibition of galectin-3. This study investigates if 30-days of G3P-01 intake in individuals with elevated galectin-3 induces biomarker changes that can be attributed to target engagement.

Study objective

Primary Objectives:
1. To evaluate target engagement attributable to G3P-01 use in volunteers with elevated galectin-3 (>= 16.0ng/mL)
2. To evaluate tolerability of G3P-01

Secondary Objectives:
1. To provide samples for research and development of analytical methods to characterize G3P-01 and its effects on the human body and for other exploratory scientific purpose related to the effects of galectin-3 on the body.

Study design

This study is a phase II randomized placebo-controlled dose ranging study in adult volunteers. Selected volunteers in the Lifelines cohort study can opt-in to have galectin-3 measured in their sample. Volunteers that meet inclusion criteria will complete a Screening visit, Enrollment visit, a Treatment Phase, a Completion visit and Follow-Up Phases.

The Screening Phase will be conducted on an outpatient basis between 14 and 1 day prior to first treatment. Participants that pass the screening phase will be invited for an enrollment visit where blood and urine samples will be collected. Subsequently, participants will be randomly assigned to one of four groups for the Treatment Phase.
Participants will be 1:1:1:1 randomized into 1 of the 3 G3P-01 dosis or placebo. The Treatment Phase will comprise of daily intake of the study product (100mg, 250mg or 1000mg of G3P-01, or placebo) for a total of 30 days.
After 30 days, blood and urine samples are collected during a Completion visit.
Participants will be contacted by phone 30±2 days after completion for follow-up.

Intervention

Study intervention: G3P-01
Dose: 0mg (placebo), 100mg, 250mg or 1000mg once daily
Treatment duration: 30 days

Study burden and risks

No G3P-01 specific health risks or concerns are known. Although unlikely because of the low dose, the occurrence of GI symptoms commonly associated with pectin intake cannot be excluded. Symptoms may include bloating, stool softening, cramps and flatulence. Pectin-products including G3P-01 may offer health benefits such as weight loss and lowered cholesterol levels, and G3P-01 may aid in the prevention of heart disease, chronic kidney disease and other consequences of fibrotic processes. Risks are limited to risks associated with common procedures such as venipuncture and study-related travel.

Contacts

Public
General Practitioners Research Institute

Prof. E.D. Wiersmastraat 5
Groningen 9713GH
NL
Scientific
General Practitioners Research Institute

Prof. E.D. Wiersmastraat 5
Groningen 9713GH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Lifelines participants who has opted in the Lifelines substudy and was found to have plasma galactin-3 levels of 16 ng/ml or higher
- Male and female subjects >=45 and <=75 years of age
- Females will be non-pregnant, non-lactating, and have no intent to become pregnant during the study period
- Able to participate in the study in the opinion of the Investigator.
- Has the ability to understand the requirements of the study and is willing to comply with all study procedures.
- An Independent Ethics Committee or in Dutch Medisch-Ethische Toetsingscommissie (METC) -approved informed consent is signed and dated prior to any study-related activities.

Exclusion criteria

- Existing clinically significant concurrent medical condition which in the opinion of the Investigator may interfere with the study.
- Clinically significant abnormal laboratory test values, as determined by the Investigator, at Screening.
- Participation in a clinical trial of an investigational drug within 30 days prior to Screening, or is currently participating in another trial of an investigational drug, supplement or device.
- Donation of greater than 100 mL of either whole blood or plasma within 30 days prior to investigational product administration.
- An immediate family or household-members of study*s personnel.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-10-2023
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	05-04-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83767.056.23

Study results

Date completed:	16-04-2024
Results posted:	10-01-2025
Actual enrolment:	48

First publication
10-01-2025

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File