A Safety/Tolerance Phase, Ascending Single Dose Study to Evaluate the Safety and Tolerability of G3P-01, a Food-Grade Pectic Product, in Healthy Volunteers

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The primary objective of the study is:* To evaluate the safety and tolerability of ascending doses of G3-P01, a food-derived pectic product administered orally in healthy adult subjectThe secondary objectives of the study are:* To collect plasma and…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51278

Source
ToetsingOnline

Brief title
G3P-01-01

Condition

- Other condition

Synonym
adverse events, safety

Health condition

safety and tolerance

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Food supplement, Galectin-3, Pectin

Outcome measures

Primary outcome

Primary endpoint(s):

* Number, severity, and nature of adverse events following the administration

of ascending doses of G3-P01:

o Number of participants with treatment emergent adverse events;

o Number of participants with clinically significant findings in physical

examinations reported

as adverse event;

o Number of participants with clinically significant change in clinical

laboratory results

reported as adverse event;

o Number of participants with clinically significant change in vital signs

reported as adverse event.

* Tolerability assessment following ascending doses of G3-P01 using the

Gastrointestinal Symptom Rating Scale (GSRS)

* Change from baseline in performance status using the Karnofsky Performance

Scale Index

Secondary outcome

Secondary endpoint(s):

* Subject to development of a suitable analytical method, the following PK

parameters on blood and urine samples following ascending doses of G3-P01:

o Maximum plasma concentration (Cmax);

o Time corresponding to the Cmax (Tmax);

o Area under the plasma concentration-time curve (AUC): from time zero to the

last non-zero concentration (AUC0-t), from time zero till 24-hours postdose

(AUC0-24), from time zero to infinity (extrapolated) (AUC0-inf);

o Elimination half-life (T1/2 el.);

o Distribution volume (Vd);

o Renal clearance (Clr).

o Dose proportionality

Study description

Background summary

Galectins are a family of soluble mammalian *-galactoside-binding lectins sharing highly conserved carbohydrate recognition domains (CRDs) consisting of ~130 amino acids (Barondes et al., 1994). Through their binding to specific carbohydrate determinants, they play a fundamental role in human and animal physiology and pathophysiology (Barrionuevo et al., 2007; Barrow et al., 2011; Camby et al., 2006; Nakahara and Raz, 2008; Paclik et al., 2011).

G3-P01 is an investigational pectin-derived Gal-3 inhibitor purified from organic, commercial squash puree intended for human consumption. G3-P01 is extracted from squash puree by a water-soluble enzymatic process, requiring no solvents, followed by ultrafiltration. The resulting product is an enriched, natural product of pectic fragments that is being developed as a nutritional therapy.

Study objective

The primary objective of the study is:
* To evaluate the safety and tolerability of ascending doses of G3-P01, a food-derived pectic product administered orally in healthy adult subject
The secondary objectives of the study are:
* To collect plasma and urine samples for research and development of analytical methods.
* To perform the plasma and urine pharmacokinetics (PK) profiling of G3-P01 after oral administration once suitable analytical methods become available.

Study design

This is an interventional, open-label, ascending dose study in 10 adult healthy volunteers.

Intervention

G3P-01 (investigational product) will be administered as a single dose during four treatment periods of 24 hours each. The doses will be ascending and will be solubilized in 100mL of water.

Study burden and risks

Pectins are generally recognizes as safe (GRAS) and in non-clinical studies have been found to be non-toxic. Participants will spend 4 days total in-unit during the study. During this time, participants will be subject to about 20 blood draws.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Male or female, aged * 18 to < 65 years;
2. Healthy volunteers, as determined by a comprehensive clinical assessment performed at screening (medical history, vital signs, clinical laboratory testing, ECG, and general physical examination);
3. Maintains a regular (mixed or vegetarian/vegan) diet.
4. Non-pregnant, non-lactating females who are either post-menopausal (natural or surgical) or are using at least one (1) of the following forms of contraception:
* Intrauterine device (IUD),
* Implantable progestogen-only hormone contraception associated with inhibition of ovulation,
* Intrauterine hormone-releasing system (IUS),
* Bilateral tubal occlusion
* Vasectomized partner
* Male or female condom with or without spermicide,
* Cervical cap, diaphragm, or sponge with spermicide,
* A combination of male condoms with either cervical cap, diaphragm, or sponge with spermicide (double-barrier methods)
* Combined (estrogen- and progestogen-containing) hormonal contraception associated with inhibition of ovulation
- oral
- intravaginal
- transdermal
- injectable
* Progestogen-only hormone contraception associated with inhibition of ovulation
- oral
- injectable
* Abstinence;
5. Willing to adhere to the prohibitions and restrictions specified in the

protocol;
6. Must be competent to understand the nature of the study and capable of giving written informed consent and be willing to report for the scheduled study visits and communicate to study personnel about adverse events and concomitant medication use.

Exclusion criteria

1. History of any clinically significant cardiac, endocrine, gastrointestinal, hematologic, hepatic, immunologic, metabolic, urologic, pulmonary, neurologic, dermatologic, psychiatric, or renal disease, or other major disease, as determined by the Investigator;
2. Clinically significant abnormal laboratory test values at screening, as determined by the Investigator;
3. Any surgical or medical condition, which in the opinion of the Investigator may pose an undue risk to the subject, interfere with participation in the study, or which may affect the integrity of the study data.
4. Any positive urine drug screen or alcohol test at Screening or clinic admission.
5. Concomitant use of any drugs known to interact with oral absorption or metabolism of pharmaceuticals, including known inducers or inhibitors of cytochrome p450 enzyme system.
6. History of alcohol abuse within 6 months prior to Screening and/or signs or symptoms of alcoholism, as determined by the Investigator.
7. Positive test for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), or Human Immunodeficiency Virus (HIV);
8. Participation in another clinical trial of an investigational drug (or medical device), or investigational food supplement within 30 days prior to screening, or currently participating in another trial of an investigational drug (or medical device), or food supplement;
9. Donation of greater than 100 mL of either whole blood or plasma within 30 days prior to investigational product administration.
10. Been informed of possible COVID-19 exposure in past 4 weeks, or recent onset of signs or symptoms of possible COVID-19 infection, including cough, shortness of breath, or temperature * 38°C.
11. Traveled via airplane or cruise ship within the last 14 days

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2022
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	28-02-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL80001.028.21