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Fermented zinc improves bioavailability

Submission date	Recruitment status	[_] Prospectively registered
31/01/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/02/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/05/2024	Other	

Plain English summary of protocol

Background and study arms
Glycoprotein matrix (GPM) nutrients are produced from a nutrient-dense broth which is cultured and bio-transformed via glycosylation by microorganisms such as yeast and/or probiotics into an advanced nutrient bound to a food source that becomes more bioavailable. This study investigates the effects of GPM on the absorption of zinc, compared to zinc oxide, commonly used as a dietary supplement.

Who can participate?
Male and female healthy volunteers, 18-55 years of age

What does the study involve?
The study involved the ingestion of the study material (GPM zinc or zinc oxide) followed by multiple blood draws.

Where is the study run from?
University of Mary Hardin-Baylor, Belton, TX, USA

When is the study starting and how long is it expected to run for?
July 2023 to January 2024

Who is funding the study?
Ashland, Kearny, NJ, USA

Who is the main contact?
Prof. Lem Taylor, University of Mary Hardin-Baylor, ltaylor@umhb.edu

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Prof Lem Taylor

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GPM Zinc

Study information

Scientific Title
Glycoprotein matrix zinc exhibits improved absorption: a randomized crossover trial

Acronym
GPM Zinc

Study objectives
The overall purpose of this study was to compare the effects of glycoprotein matrix-bound nutrients on the bioavailability of inorganic zinc oxide, commonly used as a dietary ingredient. We hypothesized that fermentation would result in greater absorption and appearance in the blood following acute ingestion while potentially reducing the incidents of gastrointestinal distress.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/10/2023, Institutional Review Board of the University of Mary Hardin-Baylor (900 College Street, Belton, TX, 76513, United States of America; +1-254-295-4553; abaggett@umhb.edu), ref: 267

Study design
Single-center interventional randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
University/medical school/dental school

Study type(s)
Other

Participant information sheet
Not available in web format

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

Interventions
Following baseline sampling, participants ingested their respective supplements with 350 mL of cold water. Blood samples will be taken at 30-, 60-, 90-, 120-, 180-, 240-, 300-, 360-, 420- and 480-minutes post-ingestion. Both zinc treatments, GPM (220mg GPM™ Soy-Free Zinc (GPM) containing 5% zinc, Ashland, Kearny, NJ, USA) and USP (zinc oxide) contained the equivalent of 11mg of zinc, 100% of the daily value and will be administered in the form of one uncoated tablet. Subjects will be randomized using random.org. A 1-week wash-out period will be implemented before subjects are crossed over to the other supplement and repeated the experimental procedure.

Intervention Type
Supplement

Primary outcome measure
The primary outcome measure in this study is plasma zinc levels measured using inductively coupled plasma/mass spectrometry (ICP/MS) at baseline, and 30-, 60-, 90-, 120-, 180-, 240-, 300-, 360-, 420- and 480-minutes post-ingestion as mcg/dL.
The zinc concentrations are used to calculate:
1. Incremental area under the concentration versus time curve (iAUC) as mcg/dL * 480 minutes
2. Maximum observed concentration (Cmax) as mcg/dL
3. The time of maximum observed concentration (Tmax) as minutes

Secondary outcome measures
Adverse events measured using the GI Health questionnaire evaluating and ranking stomach ache, abdominal pain or cramps, bloating, subjective impression of rectal gas excretion and nausea side effects on a scale from 0 (no symptoms) to 5 (severe symptoms) before and 480 minutes post-ingestion. In addition, participants will be asked to rank the severity of dizziness, headache, fast or racing heart rate, heart skipping or palpitations, shortness of breath, nervousness, blurred vision, and other unusual or adverse effects on a scale from 0 (none) to 5 (very severe).

Overall study start date
01/07/2023

Completion date
03/01/2024

Eligibility

Key inclusion criteria
1. Healthy adults
2. A normal body weight (body mass index (BMI) of 19–24.99 kg/m2)
3. Recreationally active (according to American College of Sports Medicine Guidelines)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
16

Total final enrolment
16

Key exclusion criteria
1. Currently being treated for or diagnosed with a gastrointestinal, cardiac, respiratory, circulatory, musculoskeletal, metabolic, immune, autoimmune, psychiatric, hematological, neurological or endocrinological disorder
2. Participants determined to not be weight stable defined as measured body mass deviating by 2% or more
3. Participants not willing to abstain from alcohol, nicotine, and caffeine for 12 hours before each visit

Date of first enrolment
05/10/2023

Date of final enrolment
05/11/2023

Locations

Countries of recruitment
United States of America

Study participating centre
University of Mary Hardin-Baylor
900 College St
Belton
United States of America
76513

Sponsor information

Organisation
Ashland Specialty Ingredients G.P.

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Ashland Specialty Ingredients G.P.

Results and Publications

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

Intention to publish date
01/07/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from the principal investigator, Prof. Lem Taylor, ltaylor@umhb.edu. The raw data is

available and can be shared upon written request, if the request is reasonable, as determined by the principal investigator.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/03/2024	17/05/2024	Yes	No