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In healthy adults does a novel liposomal multivitamin/mineral enhance absorption compared to a "food-based" multivitamin /mineral or standard USP multivitamin/mineral product?

Submission date
29/09/2022

Recruitment status
No longer recruiting

Registration date
04/10/2022

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dietary intervention studies among firefighters have shown improvements to oxidative stress markers that play a Multivitamin/mineral (MVM) supplements have been consumed since the early 1940s and remain one of the most popular dietary supplement categories today. Continual innovation is needed to establish products which deliver optimal doses of key vitamins, minerals, and botanicals in the most effective manner. A particularly notable development is the introduction of liposomal delivery mechanisms used to enhance absorption and maximize benefits to the consumer and have long been used as a drug delivery mechanism. Liposomes can accommodate both water-soluble and fat-soluble components and are well suited for use with the diverse properties of the vitamins and minerals contained in an MVM product. As compared to traditional methods, liposomal delivery may result in greater stability within the gastrointestinal tract, increased absorption, and ultimately greater intracellular delivery of nutrients. Despite the immense promise of this technology in general, additional research is needed to clarify the pharmacokinetic properties of specific, novel liposomal MVM formulations. Based on the favorable properties of liposomes for nutrient delivery, it is hypothesized that the liposomal MVM will exhibit greater bioavailability as indicated by higher circulating concentrations of representative micronutrients (i.e., water- and fat-soluble vitamins and minerals) when compared to a traditional MVM.

Who can participate?
Healthy volunteers aged 18 to 65 years

What does the study involve?
Phone Screening: Prospective participants will first undergo a phone screening to determine general eligibility using a standard phone script. If this screening suggests they may be a good candidate, they will be invited to a familiarization session. Familiarization: During the

familiarization, participants will be informed about the study and sign informed consent statements in compliance with the University IRB. Participants will respond to health history questionnaires; undergo a general health screening including having their height, weight, and resting heart rate and blood pressure determined; and, be informed of the general methods of the study.
Experimental 1 Testing: Participants will report to the lab after a 12 hour fast from food, dietary supplements, medications, and intake of all substances except water. Participants donate a fasting blood sample of approximately four teaspoons (~20 milliliters) of venous blood and then consume the assigned supplement along with a standardized breakfast. Blood samples will be taken 2, 4, and 6 hours following ingestion of the meal and supplement. Samples will be processed and stored at -20C until shipment. Washout Period. Participants will observe at least a 7-day washout period.
Experiment 2 Testing: Participants will report to the lab in a fasted state and repeat the experiment while consuming the next randomly assigned treatment. Washout Period. Participants will observe at least a 7-day washout period. Experiment 3 Testing: Participants will report to the lab in a fasted state and repeat the experiment while consuming the final randomly assigned treatment.

What are the possible benefits and risks of participating?
Benefits: Possible benefits of participating include determining if nutrient absorption is enhanced when a MVM supplement utilizes a novel liposomal delivery mechanism.
Risks: Possible risks of participating include slight pain when the needle is inserted during the phlebotomy procedures. Participants may develop a harmless black and blue mark, and their arm may be sore. Occasionally, some people feel dizzy or lightheaded when blood is drawn. They may become sweaty, feel cold or tingly, and may faint or throw up. Risks that are possible but unlikely include infection, nerve damage, and puncturing an artery instead of a vein. However, only a trained phlebotomist will be performing blood sampling using sterile procedures. Side effects of large doses of multivitamins may include tooth staining, increased urination, stomach bleeding, uneven heart rate, confusion and muscle weakness or limp feeling. When taken as directed, multivitamins and minerals are not expected to cause serious side effects.

Where is the study run from?
Texas A&M University (USA)

When is the study starting and how long is it expected to run for?
January 2022 for 1 month

Who is funding the study?
Better Being Company (USA)

Who is the main contact?
Dr Richard Kreider, rbkreider@tamu.edu

Contact information

Type(s)
Principal Investigator

Contact name
Dr Richard Krieder

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LIPMULT-0002

Study information

Scientific Title
Pharmacokinetic analysis of nutrient absorption from a novel liposomal multivitamin/mineral formulation

Study objectives
A novel liposomal MVM (multivitamin/mineral) improves absorption and pharmacokinetics when compared to standard USP & "food-based" MVM.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/01/2022, Texas A&M IRB (General Services Complex (GSC), Room 101A, 750 Agronomy Road, College Station, TX, 77843-1186, USA; +1 979-458-4067; irb@tamu.edu), ref: IRBID: IRB2021-1418, Study Ref# 131667

Study design
Randomized placebo controlled double-blinded triple-arm crossover intervention trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
School

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Pharmacokinetics of multivitamins in healthy adults

Interventions
Approximately 40 participants will be recruited with a goal of completing 25 in the study.
Familiarization: During the familiarization, participants will be informed about the study and sign informed consent statements in compliance with the University IRB. Participants will respond to health history questionnaires; undergo a general health screening including having their height, weight, and resting heart rate and blood pressure determined; and, be informed of the general methods of the study.
Experimental 1 Testing: Participants will report to the lab after a 12 hour fast from food, dietary supplements, medications, and intake of all substances except water. Participants donate a fasting blood sample of approximately four teaspoons (~20 milliliters) of venous blood and then consume the assigned supplement along with a standardized breakfast. Blood samples will be taken 2, 4, and 6 hours following ingestion of the meal and supplement. Samples will be processed and stored at -20C until shipment.
Washout Period. Participants will observe at least a 7-day washout period.
Experiment 2 Testing: Participants will report to the lab in a fasted state and repeat the experiment while consuming the next randomly assigned treatment.
Washout Period. Participants will observe at least a 7-day washout period.
Experiment 3 Testing: Participants will report to the lab in a fasted state and repeat the experiment while consuming the final randomly assigned treatment.

Block randomization method is used to assign to treatments:
Treatment 1 – Food Based Multivitamin (mykind Organic Women's/Men's Multi)
Treatment 2 – Non-Liposomal Universal Multivitamin
Treatment 3 – Nutraceutical Liposomal Multivitamin

Intervention Type
Supplement

Primary outcome measure
Blood samples will be taken 2, 4, and 6 hours following ingestion of the meal and supplement:
1. Area under the concentration vs. time curve (AUC)
2. Maximum observed concentration (Cmax)
3. Time of maximum observed concentration (Tmax) for each nutrient examined:
Vitamins D2/D3, A, E, C, B12, and B9 (Folic Acid), magnesium and iron

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
04/01/2022

Completion date
30/01/2022

Eligibility

Key inclusion criteria
1. Age 18 to 65 years at time of consent;
2. Ability to comply with study procedures; and,
3. Availability to complete study based on durations of individual visits and scheduling requirements.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
40

Total final enrolment
25

Key exclusion criteria
1. Presence of a disease or medical condition that could reasonably influence study outcomes or make participation inadvisable;
2. Use of medication that could reasonably influence study outcomes or make participation inadvisable;
3. Inability to abstain from medication, supplement, or substance use during the overnight fast and duration of the study visit;
4. Anticipated inability to provide blood samples (e.g., known difficulty providing blood samples); and/or
5. Currently pregnant or breastfeeding, based on self-report.

Date of first enrolment
05/01/2022

Date of final enrolment
12/01/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Texas A&M University
400 Bizzell St.
College Station
United States of America
77843

Sponsor information

Organisation
Better Being Company

Sponsor details
222 S Main St, 16th Floor
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Sponsor type
Industry

Website
https://www.betterbeing.com/

Funder(s)

Funder type
Industry

Funder Name
Better Being Company

Results and Publications

Publication and dissemination plan

Planning on publishing in Nutrients

Intention to publish date
30/11/2022

Individual participant data (IPD) sharing plan
Data and statistical analyses are available upon request on a case-by-case basis for non-commercial scientific inquiry and/or educational use if IRB restrictions and research agreement terms are not violated.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/07/2023	17/11/2023	Yes	No