ISRCTN39055102 https://doi.org/10.1186/ISRCTN39055102

Comparing how liposomal and standard formulas are absorbed in healthy adults

Submission date 13/10/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/10/2025	**Overall study status** Ongoing	
Last Edited 28/01/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Vitamin D and glutathione are important nutrients that support health, but many people struggle to absorb them effectively from standard supplements. Vitamin D deficiency affects approximately 1 billion people worldwide, partly because traditional vitamin D supplements are poorly absorbed by the body. Vitamin D needs to be taken with fat and requires bile acids to be absorbed properly in the small intestine.
Glutathione is called the body's "master antioxidant" because it protects cells from damage and supports the immune system. However, oral glutathione supplements face even bigger challenges - the nutrient breaks down quickly in the stomach and most of it is destroyed before reaching the bloodstream.
To address these absorption problems, some companies have developed liposomal formulations. Liposomes are tiny spheres made from the same material as cell membranes that can protect nutrients as they pass through the digestive system. Cymbiotika has created liposomal versions of vitamin D (combined with vitamin K2) and glutathione (combined with PQQ) that may be absorbed better than standard supplements.
This study aims to determine whether Cymbiotika's liposomal formulations are absorbed better than standard supplement forms by measuring how much of each nutrient appears in the bloodstream over time.

Who can participate?
Healthy volunteer adults aged 18-50 years with a BMI between 18.5-30 kg/m². Participants must be from the Brisbane area of Australia.

What does the study involve?
This crossover study means each participant tries both supplement types in random order. Neither participants nor researchers know which product is given at each visit (double-blind).
Individual participation: 3 weeks per supplement group.
Two groups available:
Group 1: Vitamin D3 + K2 (16 participants)
Group 2: Glutathione + PQQ (16 participants)

Vitamin D3 + K2 group (6 visits over 3 weeks):
Visit 1: Arrive fasted (no food for 10 hours). Cannula inserted, baseline blood draw, take one capsule, then a low-fat meal. Blood sampling over 10 hours. ~11 hours total.
Visit 2: Single blood draw 24 hours after dosing. ~30 minutes.
Visit 3: Single blood draw 48 hours after dosing. ~30 minutes.
Minimum 2-week washout
Visit 4: Repeat 10-hour testing with the other formulation. ~11 hours.
Visit 5: 24-hour blood draw. ~30 minutes.
Visit 6: 48-hour blood draw. ~30 minutes.

Glutathione + PQQ group (4 visits over 3 weeks):
Visit 1: Same arrival process. Standard meal 30 minutes after dosing. Blood sampling over 8 hours. ~9 hours total.
Visit 2: 24-hour blood draw. ~30 minutes.
Minimum 2-week washout
Visit 3: Repeat 8-hour testing with the other formulation. ~9 hours.
Visit 4: 24-hour blood draw. ~30 minutes.

What are the possible benefits and risks of participating?
Benefits:
Participants will receive compensation for their time and travel expenses. They will also contribute to research that could improve supplements for many people.

Risks:
The supplements are generally well-tolerated but may occasionally cause mild nausea, constipation, or vomiting.
Main risks are from blood draws:
Pain (usually brief, rarely more intense)
Bruising (common, 1 in 10 people)
Swelling (less than 1 in 1,000)
Fainting (less than 1 in 500)
Infection (very rare)

Where is the study run from?
RDC Clinical, Fortitude Valley, Brisbane, Queensland. This is a collaboration between The University of Queensland and RDC Global, Australia.

When is the study starting and how long is it expected to run for?
Enrolment will start following ethics approval (October 2025) until recruitment is completed.

Who is funding the study?
1. Cymbiotika LLC (USA) funds the study.
2. RDC Global, Australia, is the local sponsor.

Who is the main contact?
Dr David Briskey (Principal Investigator), research@rdcglobal.com.au

Contact information

Type(s)
Public

Contact name
Miss Pippa Ebelt

Contact details
RDC Global
Level 3, 252 Saint Paul's Terrace
Fortitude Valley
Australia
4006
+61 7 3102 4486
research@rdcglobal.com.au

Type(s)
Scientific, Principal investigator

Contact name
Dr David Briskey

Contact details
RDC Global
Level 3, 252 Saint Paul's Terrace
Fortitude Valley
Australia
4006
+61 7 3102 4486
research@rdcglobal.com.au

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CYMPK1

Study information

Scientific Title
A randomized, double blind crossover study to evaluate the absorption of a liposomal formulation compared to a standard comparator in healthy adult subjects.

Study objectives
It is hypothesised that the liposomal formulations will demonstrate superior bioavailability compared to standard comparators, as evidenced by significantly higher AUC values and potentially improved Cmax and Tmax profiles.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/11/2025, The University of Queensland Human Research Ethics Committee (Research Office Cumbrae Stewart Building #72, The University of Queensland, Brisbane, Queensland, 4072, Australia; +61 7 3365 3924; humanethicsadmin@research.uq.edu.au), ref: 2025/HE001712

Study design
Randomized double-blind crossover pharmacokinetic study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Bioavailability in healthy volunteers

Interventions
In this study there will be two arms:
- Arm 1: Participants will be randomly allocated to receive a single dose of either Liposomal D3 + K2 (investigational product containing D3 = 4,000 IU, K2 = 620 ug) or Standard D3 +K2 (comparator product containing D3 = 4,000 IU, K2 = 600 ug). They will then return to the clinic where they will receive a single
dosage of the alternative study product. The study products will be consumed orally.
- Arm 2: Participants will be randomly allocated to receive a single dose of either Liposomal Glutathione + PQQ (investigational product containing Glutathione = 250 mg, Pyrroloquinoline quinone = 20 mg) or Standard Glutathione + PQQ (comparator product containing Glutathione = 250 mg, Pyrroloquinoline quinone = 20 mg). They will then return to the clinic where they will receive a single dosage of the alternative study product. The study products will be consumed orally.

Intervention Type
Supplement

Primary outcome(s)
Plasma/serum uptake (AUC) of the relevant supplement (vitamin D3 and glutathione) taken over the trial period. Baseline to Day 2 (arm 2: Glutathione), Baseline to day 3 (arm 1: D3)

Key secondary outcome(s))
1. Maximum concentration (Cmax)
2. Time to maximum concentration (Tmax)
3. Individual absorption data for each subject
4. Tolerability assessment
5. Safety via adverse event monitoring
6. Non-inferiority/equivalence comparison between different formulations
7. Participant demographics and anthropometrics

Secondary endpoints will be from Baseline to Day 2 (arm 2: Glutathione) or Baseline to day 3 (arm 1: D3)

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. Males and females 18-50 years (target at least 50% female participation)
2. Generally healthy with no acute or chronic diseases
3. BMI 18.5-30 kg/m²
4. Non-smokers or former smokers who have abstained for at least 6 months
5. Able to provide informed consent
6. Able to fast for 10 hours prior to study visits
7. Using contraception (if female and sexually active)
8. Able to attend all required study visits
9. Agree to not participate in another clinical trial while enrolled in this trial
10. Agree to maintain consistent dietary and exercise patterns during study period
11. Females of childbearing potential will be required to have a negative pregnancy test on day of study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. BMI <18.5 or >30 kg/m²
2. History of cardiovascular disease, Type 2 diabetes, neurodegenerative disease, renal disease, metabolic syndrome, muscular dystrophy, or other acute/chronic diseases.
3. Gastrointestinal or absorption issues (IBD, IBS, Celiac disease, Crohn's disease, history of GI surgery, SIBO)
4. Use of statins, medications that inhibit absorption (fibrates, resins), medications affecting fat

absorption (orlistat, cetilistat), medications impacting gut integrity (corticosteroids), anticoagulants (warfarin, heparin) or medications indicative of chronic conditions within past 3 months
5. Have a serious illness1 e.g. mood disorders such as depression, anxiety or bipolar disorder, neurological disorders such as MS, kidney disease, liver disease or cardiovascular disease
6. Have an unstable illness2 e.g. diabetes and thyroid gland dysfunction
7. Current malignancy (excluding Basal Cell Carcinoma) or chemotherapy or radiotherapy treatment for malignancy within the previous 2 years
8. Vegan or following an extreme diet that may significantly affect nutrient absorption (e.g., very low-fat diets <10% calories from fat)
9. Use of any test supplements (D3, K2, Glutathione, PQQ) within 14 days prior to screening
10. Active smokers, nicotine use or drug (prescription or illegal substances) abuse
11. Chronic past and/or current alcohol use (>21 alcoholic drinks week)
12. Pregnancy, breastfeeding, or planning pregnancy during the study period
13. Unable to adhere to study protocol
14. Allergic to any of the ingredients in product formula
15. High-intensity athletic training (>10 hours structured exercise per week) that may affect metabolism
16. Participants who are currently participating in any other clinical trial or who have participated in any other clinical trial during the past 1 month
17. Any condition which in the opinion of the investigator makes the participant unsuitable for inclusion
18. Able to attend the clinic on all required days

Date of first enrolment
01/12/2025

Date of final enrolment
13/01/2026

Locations

Countries of recruitment
Australia

Study participating centre
RDC Clinical
Level 3, 252 Saint Pauls Terrace
Fortitude Valley
Australia
4006

Sponsor information

Organisation
Cymbiotika LLC

Organisation
RDC Global

Funder(s)

Funder type
Research organisation

Funder Name
Cymbiotika LLC

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available