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Effect of wild nutrition food grown formulas (magnesium and B6) on absorption in healthy adults

Submission date
10/10/2025

Recruitment status
No longer recruiting

Registration date
15/10/2025

Overall study status
Completed

Last Edited
10/06/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Magnesium and vitamin B6 are essential nutrients our bodies need but must obtain from diet or supplements. Magnesium supports over 300 body processes including energy production, muscle function, and heart health. Vitamin B6 is crucial for brain health, making chemicals like serotonin and dopamine, and supporting immune function.
Traditional supplements provide these nutrients as isolated chemical compounds, but the body doesn't always absorb them efficiently. Wild Nutrition has developed "Food Grown" formulations using a special process that incorporates nutrients into a food-like substance using beneficial bacteria and brown rice powder. The theory is that presenting nutrients in a form the body recognises as food may improve absorption compared to standard synthetic supplements. This study aims to determine whether Wild Nutrition's Food Grown supplements are absorbed better than standard forms. We'll compare Food Grown magnesium and vitamin B6 formulations against standard formulations in healthy participants. Understanding which supplements work best could help people choose more effective products for optimal health.

Who can participate?
We're seeking 32 healthy adults aged 18 and over with a BMI between 18.5-34.9 kg/m². Participants must commit to attending clinic visits on specific assigned dates, as scheduling flexibility isn't possible.
You cannot participate if you: have serious health conditions (depression, anxiety, MS, kidney /liver/heart disease); have unstable conditions like poorly controlled diabetes; have current cancer or recent cancer treatment; take long-term prescription medications (except contraceptives); are pregnant, breastfeeding, or planning pregnancy; are active smokers; consume over 21 alcoholic drinks weekly; recently made major dietary changes; or have taken magnesium or vitamin B6 supplements in the past 4 weeks.

What does the study involve?
This cross-over study means each participant tries both supplement types in random order.
Two groups available:
Group 1: Magnesium (16 participants)

Group 2: Vitamin B6 (16 participants)
Four clinic visits over 2 weeks:
Magnesium participants:
Visits 1 & 3: Arrive 7am fasted (no food since 10 pm). Cannula inserted, baseline blood draw, take one capsule, then blood samples hourly. ~9 hours each visit.
Visits 2 & 4: Single blood draw 24 hours after dosing. ~30 minutes each.
One-week washout between testing periods.
Vitamin B6 participants:
Visits 1 & 3: Same arrival process, but blood collected more freqently. ~6 hours each visit.
Visits 2 & 4: 24-hour follow-up blood draws. ~30 minutes each.
One-week washout between testing periods.
Blood samples measure how much nutrient appears in the bloodstream, how quickly, and peak concentration.
Participants must stay at clinic between blood draws but can move around freely. Once cannula is inserted, you cannot leave until it's removed for safety.

What are the possible benefits and risks of participating?
Benefits: You'll receive $500 payment for time and expenses. There are no direct health benefits from this short-term absorption study.
Risks: Both supplements are safe at doses used (80 mg magnesium, 10 mg B6). Magnesium may cause mild digestive symptoms (loose stools, nausea, bloating). Vitamin B6 may rarely cause mild nausea or headache.
Main risks are from blood draws:
1. Pain (usually brief sting, rarely more intense)
2. Bruising (1 in 10 people, usually mild)
3. Swelling (less than 1 in 1,000)
4. Fainting (less than 1 in 500)
5. Infection (very rare)

Where is the study run from?
RDC Clinical (Australia)

When is the study starting and how long is it expected to run for?
June 2025 to January 2026

Who is funding the study?
Wild Nutrition Ltd (Australia)

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

Contact information

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Additional identifiers

Protocol serial number
WILDPK-25

Study information

Scientific Title
Effect of wild nutrition food grown formulations on increasing bioavailability compared to standard formulations in otherwise healthy participants: a randomised, double-blind, cross-over study

Study objectives
It is hypothesised that Food Grown formulations will demonstrate superior bioavailability compared to standard formulations, as evidenced by higher area under the curve (AUC) values and enhanced absorption profiles for both magnesium and vitamin B6.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/11/2025, The University of Queensland Human Research Ethics Committee (Research Office Cumbrae Stewart Building #72, The University of Queensland, Brisbane, 4072, Australia; +61 (0)7 3365 3924; humanethicsadmin@research.uq.edu.au), ref: 2025/HE001684

Primary study design
Interventional

Study design

Single-centre randomized double-blind cross-over clinical study

Study type(s)
Other

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

Interventions
Current interventions as of 28/01/2026:

Randomisation will be conducted using the software available at www.sealedenvelope.com, by someone not involved in the conduct of the trial. The randomisation code for the products will be generated in a 1:1 ratio for each arm.

Group 1: Participants will be randomly allocated to receive a single dose of either 80 mg Wild Nutrition food-grown magnesium (investigational product) or 80 mg magnesium citrate (comparator). They will then return to the clinic after 1 week, where they will receive a single 80 mg dosage of the alternative study product. The study products are capsules, which will be consumed orally.

Group 2: Participants will be randomly allocated to receive a single dose of either 10 mg Wild Nutrition food-grown B6 (investigational product) or 10 mg Pyridoxin (comparator). They will then return to the clinic after 1 week, where they will receive a single 10 mg dosage of the alternative study product. The study products are capsules which will be consumed orally.

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Previous interventions:

Randomisation will be conducted using the software available at www.sealedenvelope.com, by someone not involved in the conduct of the trial. The randomisation code for the products will be generated in a 1:1 ratio for each arm.

Group 1: Participants will be randomly allocated to receive a single dose of either 80 mg Wild Nutrition food-grown magnesium (investigational product) or 80 mg magnesium bisglycinate (comparator). They will then return to the clinic after 1 week, where they will receive a single 80 mg dosage of the alternative study product. The study products are capsules, which will be consumed orally.

Group 2: Participants will be randomly allocated to receive a single dose of either 10 mg Wild Nutrition food-grown B6 (investigational product) or 10 mg Pyridoxal-5-phosphate (comparator). They will then return to the clinic after 1 week, where they will receive a single 10 mg dosage of the alternative study product. The study products are capsules which will be consumed orally.

Intervention Type
Supplement

Primary outcome(s)
1. Group 1 (Magnesium): plasma uptake of Magnesium over 24 hours (AUC) measured using colourimetric assay via a clinical chemistry analyser from baseline to 24 hours

2. Group 2 (Vitamin B6): plasma uptake of Vitamin B6 over 6 hours (AUC) measured using LC-MS-MS from baseline to 24hours

Key secondary outcome(s)
Change from baseline to the end of the study period (24 hours) in:
1. Tmax: This is calculated from the plasma values analysed in the primary outcome from baseline to 24hours.
2. Cmax This is calculated from the plasma values analysed in the primary outcome from baseline to 24hours.
3. Participant demographics (age, gender) will be collected at screening
4. Individual absorption data for each participant. This will be measured as per the measurements in the primary outcomes from baseline to 24hours.
5. Evaluate tolerability, including gastrointestinal tract tolerance. This will be measured using a Gastrointestinal Tolerance Questionnaire and reported Adverse Events from Baseline to 24 hours.
6. Non-inferiority/equivalence comparison of the formulations. This is a comparison of AUC for each group as calculated from the primary outcome measures from baseline to 24hours.
7. Safety via AE monitoring from baseline to 24 hours.

Completion date
30/01/2026

Eligibility

Key inclusion criteria
1. Adults ≥18 years
2. Generally healthy
3. Body mass index (BMI) 18.5-34.9 kg/m²
4. Able to provide informed consent
5. Agree to not participate in another clinical trial while enrolled in this trial
6. Agree not to change current diet and/or exercise frequency or intensity during entire study period
7. Participant's ability to participate fully and comply with demands of the study including attendance at all scheduled blood collection time points
8. Able to attend the clinic on all required days
9. 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
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit

100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Have a serious illness e.g. mood disorders such as depression, anxiety or bipolar disorder, neurological disorders such as MS, kidney disease, liver disease or heart conditions
2. Have an unstable illness e.g. diabetes and thyroid gland dysfunction
3. Current malignancy (excluding basal cell carcinoma) or chemotherapy or radiotherapy treatment for malignancy within the previous 2 years
4. Currently taking any long-term prescription medication (excluding contraceptive pill) (e.g., coumadin [warfarin], heparin, dalteparin, enoxaparin or other anticoagulation therapy including low dose aspirin)
5. Significant change in diet in the past 1 month (e.g., removal of a food group or calorie restriction)
6. Active smokers, nicotine use or drug (prescription or illegal substances) abuse
7. Chronic past and/or current alcohol use (>21 alcoholic drinks week)
8. Pregnant or lactating women
9. Allergic to any of the ingredients in either formulation
10. Participants who are currently participating in any other clinical trial.
11. Any condition which in the opinion of the investigator makes the participant unsuitable for inclusion
12. Regular use within the past 4 weeks of supplements containing the compound being tested (magnesium for Arm 1 and Vitamin B6 for Arm 2)

Date of first enrolment
01/12/2025

Date of final enrolment
09/01/2026

Locations

Countries of recruitment
Australia

Study participating centre
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Sponsor information

Organisation
Wild Nutrition Ltd

Organisation
RDC Global

Funder(s)

Funder type
Industry

Funder Name
Wild Nutrition Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr David Briskey, research@rdcglobal.com.au

IPD sharing plan summary
Available on request