

Study Details | NCT07210684 | Effects of Dihydroberberine (DHB) on GLP-1, Glycemic Control, Appetite, and Mood in Adults With Pre-Diabetes

 clinicaltrials.gov/study/NCT07210684

Effects of Dihydroberberine (DHB) on GLP-1, Glycemic Control, Appetite, and Mood in Adults With Pre-Diabetes (DHB)

ClinicalTrials.gov ID NCT07210684

Sponsor Nanjing Nutrabuilding Bio-tech Co., Ltd.

Information provided by Nanjing Nutrabuilding Bio-tech Co., Ltd. (Responsible Party)

Last Update Posted 2025-10-07

Study Overview

The goal of this clinical trial is to learn if Dihydroberberine (DHB) supplementation affects adults with pre-diabetes.

The main questions it aims to answer are:

Does DHB supplementation increase the concentration of GLP-1 in the blood? Does DHB supplementation affect appetite, mood, and energy levels? Does DHB supplementation affect body weight, blood sugar control and insulin? Researchers will compare DHB supplementation to a placebo (a look-alike substance that contains no drug) to see if DHB has any effect.

Participants will:

Take DHB or a placebo every day for 6 weeks. Participate in tests to measure GLP-1 levels, blood glucose, insulin and other markers.

Have their continuous blood sugar profiles (with CGMs) monitored to see how much time their blood sugar spends in a healthy range.

Rate their appetite, mood, and energy levels using a visual analog scale.

A Randomized, Double-Blind, Placebo-Controlled Trial on the Effects of Dihydroberberine (DHB) on Glucagon-Like Peptide-1 (GLP-1), Glycemic Control, and Subjective Rating of Appetite and Mood/Energy in Adults With Pre-Diabetes

- Dietary Supplement: Placebo 400 mg

- Dietary Supplement: Dihydroberberine (DHB) 400 mg

STERLING IRB ID: 14195-EAAntoo

Primary Completion (Estimated)

2026-01-15

Study Completion (Estimated)

2026-03-15

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](#).

Name: Kotryna Dzekcioriute

Phone Number: (630) 617-2000

Email: kotryna.dzekciouriute@mxns.com

Name: Elizabeth Antoo, MD

Phone Number: (630) 617-2000

Email: elizabeth.antoo@mxns.com

This study has 1 location

Addison, Illinois, United States, 60101

Recruiting

Merieux NutriSciences

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Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#).

Inclusion Criteria:

1. 35 - 65 years of age (inclusive).
2. BMI 25.0 - 35.0 kg/m² (inclusive).
3. HbA1c 5.7% - 6.4% (39 - 47 mmol/mol, inclusive) measured at visit 1.
4. Participant has a score of 7 - 10 on the Vein Access Scale Assessment at visit 1.
5. Non-user or former user (daily use; cessation $\geq$ 12 months) of tobacco or nicotine products (e.g., cigarette smoking, vaping, chewing tobacco) within 12 months of visit 1, and has no plans to begin use during the study period.
6. Non-habitual users (i.e., daily or almost daily) of marijuana or hemp products, including CBD/THC products, and willing to abstain from use throughout the study period (topical creams/lotions are allowed).
7. Willing to wear a CGM sensor throughout study period and willing to adhere to instructions/restrictions associated with the proper use and care of the CGM.
8. Willing to use personal smart phone with operating system capable of downloading and operating the Cronometer and Dexcom CGM apps for diet records and blood glucose, respectively.
9. Willing to adhere to all study procedures, including lifestyle considerations, and sign forms providing informed consent to participate in the study and authorization to release relevant protected health information to the Clinical Investigator.

Exclusion Criteria:

1. Extreme Diets: Extreme dietary habits (e.g., ketogenic, vegan/vegetarian) at investigator's discretion.
2. Intense Exercise: Moderate-to-intense physical training ($\geq$ 5 hours/week).
3. Weight Instability/Program: Recent weight changes (>4.5 kg $\leq$ 90 d) or current/planned weight change program.
4. Abnormal Labs: Abnormal lab test results of clinical significance at Visit 1 (one re-test allowed).
5. Uncontrolled Chronic Illness: Uncontrolled or clinically important pulmonary, cardiac, hepatic, renal, endocrine (T1D/T2D excluded), hematologic, immunologic, neurologic, psychiatric, or biliary disorders.
6. Clinically Important GI: Clinically important GI condition interfering with study product (e.g., IBD, celiac, weight loss surgery history).
7. Uncontrolled HTN: Uncontrolled hypertension (SBP $\geq$ 160 mmHg and/or DBP $\geq$ 100 mmHg).

8. Cancer History: History or presence of cancer in the prior 2 years (except non-melanoma skin cancer).
9. Active Infection: Signs/symptoms of active infection ≤ 5 d of Visit 1.
10. Anti-Hyperglycemics: Recent use (≤ 6 mo) of any prescription anti-hyperglycemic medication.
11. Other Supplements: Use of dietary supplements (other than approved multivitamin) ≤ 14 d of Visit 1.
12. Alcohol/Substance Abuse: History (≤ 12 months) of alcohol (> 14 drinks/week) or substance abuse.
13. Antibiotics: Antibiotic use ≤ 90 d of Visit 1.
14. Regular NSAIDs: Regular use (≥ 3 days/week ≤ 30 d) of anti-inflammatory medications.
15. Steroid Use: Recent use (≤ 30 d) of oral/injectable steroids, or high-dose topical/inhaled steroids.
16. Unregistered Drug: Exposure to any non-registered drug product ≤ 30 d prior to Visit 1
17. Medication Instability: Unstable dose (≤ 90 d) of any other prescription medications (PRN excluded).
18. Psychiatric Hospitalization: Major affective/psychiatric disorder requiring hospitalization ≤ 12 months prior to Visit 1.
19. Recent Trauma/Surgery: Major trauma or any surgical event ≤ 30 d of Visit 1.
20. Recent GI Prep: Endoscopy or colonoscopy preparation ≤ 90 d prior to Visit 1.
21. Planned Surgery: Scheduled or planning elective surgical procedures during the study.
22. Female Status: Pregnancy, lactation, planning pregnancy, or unwillingness to use approved contraception.
23. Allergies: Known sensitivity or allergy to any study products or foods.
24. Investigator Discretion: Any condition that interferes with compliance, confounds results, or presents undue risk.

35 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study

Accepts Healthy Volunteers

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Primary Purpose : Other

Allocation : Randomized

Interventional Model : Parallel Assignment

Masking : Quadruple (Participant/Care Provider/Investigator/Outcomes Assessor)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment
Placebo Comparator: Placebo	Dietary Supplement: Placebo 400 mg Participants will receive 4 placebo capsules daily for 6 weeks. Each capsule contains 100 mg of microcrystalline cellulose, which serves as a inactive control substance.
Experimental: Dihydroberberine (DHB)	Dietary Supplement: Dihydroberberine (DHB) 400 mg Participants will receive 4 capsules of DHB (Dihydroberberine) 100 mg each, orally, once daily for 6 weeks. The total daily dose is 400 mg of DHB.

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in Postprandial Total GLP-1 Cmax After Single Dose of DHB	Change in postprandial total glucagon-like peptide-1 (GLP-1) maximum concentration (Cmax) following a single dose of 200 mg DHB compared to placebo, measured at visit 3, day 0.	Visit 3, Day 0 (after single dose administration)
Change in GLP-1 Cmax From Baseline to End of Study After 6 Weeks of DHB	Change in postprandial total GLP-1 maximum concentration (Cmax) from baseline to end of study after 6 weeks of daily supplementation with 400 mg DHB vs. placebo.	Baseline to End of Study , approximately Week 6

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Change in Postprandial GLP-1 AUC (piAUC0-120min) After Single Dose of DHB	Positive incremental AUC (piAUC0-120min) as calculated by the linear trapezoid method where the fasting levels will be subtracted from post-product consumption time points and levels lower than baseline will be truncated at 0	0-120 minutes post-meal at Baseline and Acute Visit 3, Day 0
Change in Time to Maximum Concentration (Tmax) of Postprandial GLP-1 After Single Dose of DHB		0-120 minutes post-meal at Baseline and Acute Visit 3, Day 0
Change in Fasting Total GLP-1 Levels from Baseline (day -7) to the Acute Visit 3 (day 0)		From Baseline (Visit 2, Day -7) to Acute Visit (Visit 3, Day 0)
Postprandial Glucose and insulin Responses After Single Dose	Postprandial responses of plasma glucose and insulin during MTT at visit 3, day 0 after single-dose DHB (200 mg) vs. placebo, including: 1. maximum concentration (Cmax) ; 2. time to peak (Tmax) ; 3. positive incremental AUC (piAUC0-120min) ; 4. fasting levels.	0-120 minutes post-meal at Visit 3, Day 0

Outcome Measure	Measure Description	Time Frame
Change in Subjective Appetite Perceptions After Single Dose of DHB	Appetite VAS ratings quantified by the following metrics : (1) 0-120 min net incremental AUC (niAUC0-120min) as calculated by the linear trapezoid method where the baseline values (measured at t = -45 min) will be subtracted from post product consumption time points ; 1. Composite appetite score ([desire to eat + hunger + (100 - fullness) + prospective consumption]/4) ; 2. Individual VAS ratings: Hunger; Desire to eat; Fullness; Prospective food consumption ; (2) Positive maximum response (i.e., change from the fasted value t = -45 min) appetite for composite and individual VAS ratings ; (3) Fasting (t = -45 min) appetite for composite and individual VAS ratings ;	0-120 minutes post-meal at Visit 3, Day 0
Time In/Out of Range of 24-Hour Continuous Glucose Monitoring (CGM) Glycemic Health Endpoints	1. Time In Range (TIR) and percentage of TIR where the target range is 70 - 180 mg/dL ; 2. Time In Tight Range (TITR) and percentage of TITR where the tight target range is 70 - 140 mg/dL ; 3. Time above range and the percentage of readings >180 mg/dL ; 4. Time below range and the percentage of readings < 70 mg/dL.	24 hours following product intake (Visit 3, Day 0)
Mean Glucose and Variability of 24-Hour Continuous Glucose Monitoring (CGM) Glycemic Health Endpoints	1. Change in Mean 24-Hour Glucose: Mean glucose averaged over the 24 collection period ; 2. Glycemic Variability (Coefficient of Variation (CV)): Glycemic variability defined by the Standard Deviation (SD) and CV over the 24 h collection period.	24 hours following product intake (Visit 3, Day 0)

Outcome Measure	Measure Description	Time Frame
Change in Postprandial GLP-1 (piAUC0-120min) After 6 Weeks of Supplementation	Change in positive incremental area under the curve (piAUC0-120min) for plasma total GLP-1 during the Meal Tolerance Test (MTT) from baseline (Visit 2, Day -7) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, calculated using the linear trapezoidal method.	Baseline (Visit 2, Day -7) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Postprandial Total GLP-1 Time to Maximum Concentration (Tmax) from Baseline to Week 6	Change in the Time to Tmax of plasma total GLP-1 during the MTT from baseline (Visit 2, Day -7) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo	Baseline (Visit 2, Day -7) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Fasting Plasma Total GLP-1 Levels from Baseline to Week 6	Change in fasting plasma total GLP-1 levels from baseline (Visit 2, Day -7) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo.	Baseline (Visit 2, Day -7) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Postprandial Plasma Glucose Maximum Concentration (Cmax) from Baseline After 6 Weeks of Supplementation	Change in plasma glucose dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6

Outcome Measure	Measure Description	Time Frame
Change in Postprandial Plasma Glucose Time to Peak Concentration (Tmax) from Baseline After 6 Weeks of Supplementation	Change in plasma glucose dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Postprandial Plasma Glucose Positive Incremental Area Under the Curve (piAUC0-120min) from Baseline After 6 Weeks of Supplementation	Change in plasma glucose dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Fasting Plasma Glucose Levels from Baseline to Week 6	Change in plasma glucose dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6

Outcome Measure	Measure Description	Time Frame
Change in Postprandial Plasma Insulin Time to Peak Concentration (Tmax) from Baseline After 6 Weeks of Supplementation	Change in plasma insulin dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Postprandial Plasma Insulin Positive Incremental Area Under the Curve (piAUC0-120min) from Baseline After 6 Weeks of Supplementation	Change in plasma insulin dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Fasting Plasma Insulin Levels from Baseline to Week 6	Change in plasma insulin dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) After 6 Weeks	Change in insulin resistance index from baseline (Visit 2) to end of study (Visit 4) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo. HOMA-IR is calculated as [fasting insulin (mU/L) × fasting glucose (mg/dL)] / 405.	Baseline (Visit 2) to End of Study (Visit 4), approximately Week 6

Outcome Measure	Measure Description	Time Frame
Change in Postprandial Insulin Maximum Concentration (Cmax) from Baseline to Week 6	Change in plasma insulin dynamics from baseline (Visit 2, day 0) to end of study (Visit 4, Day 42) following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo, assessed during the MTT.	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6
Change in Appetite Perceptions for composite VAS ratings After 6 Weeks of Supplementation	Change in appetite VAS ratings from baseline (Visit 2) to the end of study (Visit 4) : 1. niAUC0-120min appetite for composite VAS ratings 2. Positive maximum response appetite for composite VAS ratings 3. Fasting appetite for composite VAS ratings The Appetite Visual Analog Scale (VAS) is used to assess subjective feelings of appetite. This VAS contains four questions related to appetite (hunger, desire to eat, fullness, and prospective food consumption). The scores are interpreted as follows: composite appetite where lower scores indicate less appetite; hunger where lower scores indicate less hunger; desire to eat where lower scores indicate less desire to eat; fullness where high scores indicate more fullness; prospective food consumption where lower scores indicate less prospective food consumption.	Baseline (Visit 2, Day -7) to End of Study (Visit 4, Day 42), approximately Week 6

Outcome Measure	Measure Description	Time Frame
Change in Appetite Perceptions for individual VAS ratings After 6 Weeks of Supplementation	Change in appetite VAS ratings from baseline (Visit 2) to the end of study (Visit 4) : 1. niAUC0-120min appetite for individual VAS ratings 2. Positive maximum response appetite for individual VAS ratings 3. Fasting appetite for individual VAS ratings The Appetite Visual Analog Scale (VAS) is used to assess subjective feelings of appetite. The scale consists of a continuous line that ranges from 0 to 100 mm. The four specific scale items assessed during the MTT are: 1. How hungry do you feel? (Anchor: 0 = Not hungry at all; 100 = As hungry as I have ever felt) 2. How strong is your desire to eat? (Anchor: 0 = Not strong at all; 100 = As strong as I have ever felt) 3. How full do you feel? (Anchor: 0 = Not full at all; 100 = As full as I have ever felt) 4. How much food do you think you can eat? (Anchor: 0 = Nothing at all; 100 = A large amount)	Baseline (Visit 2, day 0) to End of Study (Visit 4, Day 42), approximately Week 6

Outcome Measure	Measure Description	Time Frame
Time In/Out of Range of 7-Day Continuous Glucose Monitoring (CGM) Parameters After 6 Weeks	1. Time In Range (TIR) and percentage of TIR where the target range is 70 - 180 mg/dL ; 2. Time In Tight Range (TITR) and percentage of TITR where the tight target range is 70 - 140 mg/dL ; 3. Time above range and the percentage of readings >180 mg/dL ; 4. Time below range and the percentage of readings <70 mg/dL.	7-day monitoring period before Visit 2 (Day -7) and Visit 4 (Day 42)
Mean Glucose Averaged and Variability of Over 7 Days from Baseline to Week 6	1. Mean glucose averaged over the 7-day collection period ; 2. Glycemic variability defined by the SD and CV over the 7-day collection period.	7-day monitoring period before Visit 2 (Day -7) and Visit 4 (Day 42)
Outcome Measure	Measure Description	Time Frame
Change in Body Weight After 6 Weeks of DHB Supplementation	Change in body weight from day 0 to day 42 following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo.	Baseline to End of Study (Day 42), approximately Week 6

Outcome Measure	Measure Description	Time Frame
Change in Perceived Energy After 6 Weeks of DHB Supplementation	Change in energy VAS rating from day 0 to day 42 following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo. The title of scales is Mental and Physical State Energy and Fatigue State Scales (EFSS). The Energy VAS will be the 6-item Mental and Physical State Energy and Fatigue Scale where participants rate their current subjective feelings of physical and mental energy and fatigue. Energy is a composite score of answers regarding energy, vigor, and pep. Fatigue is a composite score regarding fatigue, exhaustion, and worn-out. Respective individual scores are summed to composite scores ranging from 0 to 300.	Baseline to End of Study (Day 42), approximately Week 6
Change in Mood Status After 6 Weeks of DHB Supplementation	Change in Profile of Mood States (POMS) scores from day 0 to day 42 following 6 weeks of daily DHB supplementation (400 mg/day) vs. placebo. The title of scale is Profile of Mood States (POMS). The POMS-2 is a self-report assessment of mood. The POMS-2 can be evaluated for a composite total mood disturbance score and 6 component scores of anger-hostility, confusion-bewilderment, depression-dejection, fatigue-inertia, tension-anxiety, and vigor-activity.	Baseline to End of Study (Day 42), approximately Week 6

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Biofortis, Merieux NutriSciences

Principal Investigator: Elizabeth Antoo, MD, Biofortis, Inc. Merieux NutriSciences

Publications

Study Results

These publications are provided voluntarily by the person who enters information about the study and are about the results of the study.

- [Moon JM, Ratliff KM, Hagele AM, Stecker RA, Mumford PW, Kerksick CM. Absorption Kinetics of Berberine and Dihydroberberine and Their Impact on Glycemia: A Randomized, Controlled, Crossover Pilot Trial. Nutrients. 2021 Dec 28;14\(1\):124. doi: 10.3390/nu14010124.](#)
- [Panigrahi A, Mohanty S. Efficacy and safety of HIMABERB\(R\) Berberine on glycemic control in patients with prediabetes: double-blind, placebo-controlled, and randomized pilot trial. BMC Endocr Disord. 2023 Sep 7;23\(1\):190. doi: 10.1186/s12902-023-01442-y.](#)

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

First Submitted that Met QC Criteria

Last Update Submitted that Met QC Criteria