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Efficacy of human milk supplementation on performance and adaptations

Submission date
21/01/2026

Recruitment status
No longer recruiting

Registration date
26/01/2026

Overall study status
Completed

Last Edited
23/01/2026

Condition category
Other

[ ] 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
Human milk oligosaccharides (HMOs) are abundant in human breast milk and play an essential role in growth and development. For example, the HMO 6'-Sialyllactose (6'-SL) has been reported to possess anti-inflammatory effects and promote immune function, brain development, and gut health. Spadaro et al. reported that 6'-SL administration increased endurance during swimming in a Caenorhabditis elegans model. Recent studies under peer review found that 6'-SL supplementation (oral ingestion of 100 mg/kg for 12 weeks) increased markers of muscle oxidative status and decreased blood lactate during exercise, suggesting a less anaerobic contribution to the exercise task. Additionally, 6'-SL supplementation (100 mg/kg oral ingestion for 12 weeks) increased muscle mass and strength. This proof-of-concept clinical trial aims to determine whether 6'-SL supplementation during resistance training affects exercise performance, body composition, and strength adaptations in men. Young men will be examined in this initial proof-of-concept study since they are the primary consumers of muscle-building and performance-enhancement supplements and to reduce variation from sex differences in this initial pilot study.

Who can participate?
Young healthy volunteer men aged 18 to 40 years

What does the study involve?
Participants will be allocated 6'-SL supplementation (900 mg/d for 12 weeks) during resistance training and the affects exercise performance, body composition, and strength adaptations will be investigated.

What are the possible benefits and risks of participating?
Benefits and risks not provided at the time of registration

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

When is the study starting and how long is it expected to run for?
April 2025 to December 2025

Who is funding the study?
GeneChem Inc, South Korea.

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

Contact information

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Study information

Scientific Title
Efficacy of human milk oligosaccharide 6'-sialyllactose supplementation on exercise performance and training adaptations

Acronym
GeneChem Study

Study objectives
The goal of this study is to determine whether dietary supplementation of 6'-SL supplement (900 mg/day for 12 weeks) enhances the benefits of participation in a resistance-training program.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/01/2025, Texas A&M University (TAMU) Institutional Review Board (IRB) (301 Old Main Drive Suite #3104, College Station, 77843, United States of America; 979-845-8585; irb@tamu.edu), ref: STUDY2024-1110

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Health services research

Study type(s)

Health condition(s) or problem(s) studied
Dietary supplementation of 6'-SL supplement (900 mg/day for 12 weeks) to enhance the benefits of participation in a resistance-training program.

Interventions
All participants will participate in an exercise training program (two upper body and two lower body workouts per week, consisting of a five-minute warm-up, light stretching, and a periodized resistance training program designed to improve strength and muscle mass that includes all body parts). Additionally, participants will participate in an interval conditioning program designed to increase anaerobic threshold (slow walk for two minutes followed by one-minute

intervals at a workload exceeding 80% of Heart Rate Reserve (HRR), repeated five times with heart rate and workloads monitored).

Participants will be randomly allocated using block randomisation to the supplements. All participants will be instructed to ingest one of the following supplements every day with breakfast, lunch and dinner for 12 weeks:
Treatment 1: Placebo (3 x 300 mg of maltodextrin)
Treatment 2: 6'-SL (3 x 300 mg)

Intervention Type
Supplement

Primary outcome(s)
1. Blood lactate (milligrams per deciliter (mg/dl)) measured using a Nova Biomedical portable lactate meter at baseline, 6 and 12 weeks post

2. Body Composition (% body fat) measured using Hologic Discovery W Dual-Energy X-ray Absorptiometry (DXA) at baseline, 6 and 12 weeks post

3. Estimated 1 Repetition Maximum (1 RM) pounds (lbs) measured using a standard 1 RM protocol on the Nebula brand standard bench press at baseline, 6 and 12 weeks post

4. Estimated 1 Repetition Maximum (1 RM) pounds (lbs) measured using a standard 1 RM protocol on the Nebula brand standard hip/leg press at baseline, 6 and 12 weeks post

Key secondary outcome(s))
1. Ventilatory anaerobic threshold (milliliters of oxygen per minute (mL/min)) measured using ParvoMedics True One 2400 Metabolic Cart at baseline, 6 and 12 weeks post

2. Anaerobic capacity in watts per kilogram (W/kg) measured using a standard Wingate anaerobic capacity test on a Lode Excalibur Sport bicycle ergometer at baseline, 6 and 12 weeks post

3. Upper body changes in muscle endurance measured using a Nebula brand standard bench press by recording the number of repetitions at 70% 1 RM at baseline, 6 and 12 weeks post

4. Lower body changes in muscle endurance measured using a Nebula brand standard hip/leg press by recording the number of repetitions at 70% 1 RM at baseline, 6 and 12 weeks post

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. Has given voluntary, written, informed consent to participate in the study
2. Healthy males between the ages of 18 - 40 years
3. Body Mass Index (BMI) less that 40 kg/m2 and/or body fat < 35%
4. Recreationally active individuals capable of performing a whole-body resistance-training and moderate-intensity aerobic exercise program
5. Willing to maintain consistent sleep duration the evening before the study visits

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Male

Total final enrolment
19

Key exclusion criteria
1. Plan major changes in lifestyle (i.e., diet, dieting, exercise levels, travel) during the study
2. Have a recent history (< 3 months) of exercise training or weight loss (>5%)
3. Have an orthopedic limitation that would prevent participation in a general fitness program
4) Have uncontrolled heart disease, hypertension, diabetes, thyroid disease, cancer, neurological disease, or untreated psychotic or major depressive disorder
5. Have taken muscle-building supplements (e.g., creatine, protein) during the last four weeks or medications that may affect muscle mass or exercise training adaptations
6. Have a known allergy to milk protein
7. Inability to commit to perform and complete the 12-week training program

Date of first enrolment
01/04/2025

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
United States of America

Sponsor information

Organisation
GeneChem Inc

Funder(s)

Funder type

Funder Name
GeneChem Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available