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Is the artificial sweetener, sucralose, linked to gastrointestinal disruption during exercise?

Submission date 10/08/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/08/2026	**Overall study status** Completed	
Last Edited 10/08/2026	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
The impact of oral sucralose ingestion during exercise on markers of gastrointestinal discomfort and damage among healthy adults

Study objectives
The purpose of this study is to examine the effects of oral ingestion of sucralose during exercise on markers of gastrointestinal discomfort and damage.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/01/2017, Central Michigan University Institutional Review Board 1 (Foust 104, Mount Pleasant, 48859, United States of America; +1 (0)9897746401; irb@cmich.edu), ref: 988458-2

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Placebo

Assignment
Sequential

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Physically active adults with no known cardiopulmonary, metabolic, or immune disorders

Interventions
Ten healthy volunteers (aged 19-30 years) who exercise regularly will be recruited into a randomized controlled trial with a crossover design. Randomization will be sequential.

The initial visit will be to answer a health history questionnaire, and perform baseline testing (body composition testing and a maximal exercise test).

Additional visits will consist of ingesting a small dose of sucralose (44 mg) or a water placebo at rest, and during exercise. The exercise will be a 60-minute treadmill run/walk at 70% intensity. Venous blood (10 ml, 0.675 tbsp) will be collected during each visit to the lab to measure plasma markers of gastrointestinal distress.

Intervention Type
Supplement

Primary outcome(s)
1. Gastrointestinal barrier integrity: intestinal fatty acid binding protein (I-FABP) levels in plasma measured using an enzyme-linked immunosorbent assay (ELISA) at baseline (pre) and immediately after exercise

2. Gastrointestinal damage: claudin-3 (CLDN-3) levels in plasma measured using an enzyme-linked immunosorbent assay (ELISA) at baseline (pre) and immediately after exercise

3. Gastrointestinal discomfort measured using a 1-5 point Likert scale at baseline (pre) and immediately post exercise

4. Gastrointestinal symptoms measured using a 0-9 point scale at the post-exercise timepoint only

Key secondary outcome(s)

Completion date
01/05/2017

Eligibility

Key inclusion criteria
Physically active runners - running more than 60 minutes continuously each week

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
19 Years

Upper age limit
30 Years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Known gastrointestinal, liver, seizure, or kidney disorder
2. Taking certain medications (nonsteroidal anti-inflammatory drugs [NSAIDs], antidepressants, or diuretics); nutritional supplements, including proteins, creatine, amino acids (e.g., branched-chain amino acids [BCAAs], glutamine, taurine), antioxidants (e.g., turmeric, curcumin, sulforaphane, omega-3), and prebiotics and probiotics

Date of first enrolment
01/02/2017

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
United States of America

Sponsor information

Organisation
Central Michigan University

ROR
https://ror.org/02xawj266

Funder(s)

Funder type

Funder Name
Central Michigan University

Alternative Name(s)
Central Michigan Normal School and Business Institute, Central Michigan Normal School, CMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available