The effect of acute ketone monoester supplementation on glucose oxidation during exercise performed with high rates of carbohydrate ingestion in trained cyclists

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The purpose of this study is to examine the effect of exogenous ketone body supplementation on carbohydrate metabolism during exercise.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53385

Source
ToetsingOnline

Brief title
Ketone study

Condition

- Other condition

Synonym
energy metabolism; fuel selection during exercise

Health condition

This study will evaluate the effect of exogenous ketone mono-ester supplementation on endogenous and exogenous carbohydrate metabolism during exercise

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Carbohydrate, Cycling, Ketone, Oxidation

Outcome measures

Primary outcome

Comparing exogenous glucose oxidation during exercise between the ketone monoester and placebo conditions

Secondary outcome

- Endogenous glucose disappearance rate
- Exogenous glucose disappearance rate
- Total glucose disappearance rate
- Exogenous glucose appearance rate
- Endogenous glucose appearance rate
- Total glucose appearance rate
- Plasma glucose enrichments

Tertiary

- Total carbohydrate oxidation indirectly by using traditional stoichiometric calculations of carbohydrate oxidation
- Plasma glucose, insulin, lactate, glycerol, and ketone body concentrations (including area under the curve) following drink ingestion

- Exercise economy

- Mean exercise heart rate

- Data for subject characteristics (i.e. age, weight, height, peak oxygen

uptake)

Study description

Background summary

Recently, there has been a re-emerging interest in the role of ketone bodies in exercise metabolism. Ketone bodies can serve as an important energy substrate under certain conditions, such as starvation, and can modulate carbohydrate and lipid metabolism. However, the extent to which acute ketone body supplementation regulate skeletal muscle bioenergetics and substrate metabolism during prolonged endurance-type exercise remains to be determined. Therefore, it is of importance to perform direct measures of substrate utilization after supplementation with ketone bodies. With respect to carbohydrate use, neither endogenous nor exogenous carbohydrate oxidation have been determined. Thus, direct measures of endogenous and exogenous carbohydrate oxidation will help clarify the effects of acute ketone body supplementation on substrate oxidation.

Study objective

The purpose of this study is to examine the effect of exogenous ketone body supplementation on carbohydrate metabolism during exercise.

Study design

Randomized, crossover, and double-blind

Intervention

The acute interventions will involve ingestion of carbohydrates with either a ketone monoester supplement before (0.35 g/kg body mass) and throughout (0.20 g/kg body mass per hour) the 3-hour exercise session or flavour-matched ketone-free placebo.

Study burden and risks

Participants will be required to report to the laboratory for a total of 3 visits, comprised of 1 screening visit (~2 h), and 2 experimental visits (each ~6 h). Participants will have to record their diet and activity patterns for 72 h prior to the 2 experimental visits and duplicate these patterns before the 2 experimental visits. The potential risks and discomforts inherent to the exercise testing procedure during each visit are minimal and are similar to those associated with any form of strenuous physical activity including fatigue, fainting, abnormal blood pressure, etc. Subjects will provide 10 blood samples during each experimental visits (20 total for the study). Insertion of the catheters in a vein is comparable to a normal blood draw and the only risk is a small local hematoma.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- 18-50 years of age
- Trained cyclist/triathlete ((VO2peak > 55 ml/kg/min for males and >48 ml/mg/min for females)
- Healthy as per medical history and investigator*s/physician*s judgement
- Having given written informed consent

Exclusion criteria

- Use of medication that could impact study outcomes and/or interfere with the expected mechanism of action of ketone supplements (e.g. Chronic use of gastric acid suppressing medication, statins, corticosteriods)
- Smoking
- Diagnosed acute or chronic medical conditions that, in the opinion of the investigator, could impact study outcomes (e.g. Diabetes mellitus)
- Diagnosed musculoskeletal disorders
- Adhering to a carbohydrate restrictive diet
- Participation in another study at the same time
- Blood donation in the 2 months before the first experimental trial
- Plasma donation in the 2 weeks before the first experimental trial
- Males: VO2peak <55 ml/min/kg body mass
- Females: VO2peak <48 ml/min/kg body mass
- Females: pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-03-2024
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83622.068.23
Other	will be done after METC approval