The effect of a potato based low-osmolaric glucose polymer drink on gastric distress and running performance*

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To investigate whether two newly developed, potato based LOPG drinks with a different osmolarity and volume taken before exercise, differently affect gastric distress after both a short and long term exercise, running performance, and the rate of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON40832

Source
ToetsingOnline

Brief title
LOGP drink for gastric distress and running performance

Condition

- Gastrointestinal signs and symptoms

Synonym
gastric complaints, Gastric distress

Research involving
Human

Sponsors and support

Primary sponsor: AVEBE U.A.

Source(s) of monetary or material Support: AVEBE U.A.,Commercieel bedrijf (AVEBE U.A.)

Intervention

Keyword: Gastric complaints, Gastric emptying, Low-osmolaric glucose polymer, Sports drink

Outcome measures

Primary outcome

The perceived degree of gastric distress after both short and long term

exercise performance, and finishing times at a running event of 10 km.

Secondary outcome

The gastric emptying rate, and blood glucose levels.

Study description

Background summary

Sports drinks are a convenient source of carbohydrates (CHO) before or during exercise. However, due to the high osmolarity of CHO in solutions, CHO drinks can cause gastric distress during running exercise. Consequently, this can lead to a reduction is running performance. A newly developed low osmolaric glucose polymer (LOGP) drink derived from potato starch may lead to a reduced incidence of gastric distress, and therefore preserve running performance.

Study objective

To investigate whether two newly developed, potato based LOPG drinks with a different osmolarity and volume taken before exercise, differently affect gastric distress after both a short and long term exercise, running performance, and the rate of gastric emptying compared to an isoenergetic CHO control.

Study design

This is a randomised placebo-controlled trial with a cross-over design. This study consist of three parts. Firstly, 40 participants will partake in the 3 km-test sessions involving running 3 km to their best extent, after which they

will fill in a questionnaire concerning gastric complaints. They will perform three 3 km-test sessions, consuming intervention drink 1, intervention drink 2, and the control drink each once in a crossover fashion, 15 minutes before exercise. Secondly, all participants will be divided in either intervention group 1, intervention group 2, or the control group, based on their performance in the 3 km-test. All participants will partake in an event test which involves performing in a running event of 10 km, after which they will fill in a questionnaire concerning gastric distress. The test drink will be consumed 15 minutes before exercise. Thirdly, a subselection of 10 out of the 40 participants will be enrolled in the gastric emptying test sessions. These sessions involve undergoing a (1-13C)-sodium acetate breath test and blood glucose measurements. They will perform three sessions, consuming intervention drink 1, intervention drink 2, and the control drink each once.

Intervention

The treatment involves taking a CHO solution. Intervention drink 1 consists of 40 g LOGP in 400 mL fluid (10 g CHO*100 ml-1) with an osmolarity of 113 mosmol*kg-1. Intervention drink 2 consists of 40 g LOGP in 200 ml fluid (20 g CHO*100 ml-1) with an osmolarity of 205 mosmol*kg-1. The control drink consists of 40 g maltodextrin in 400 ml fluid (10 g CHO*100 ml-1) with an osmolarity of 300 mosmol*kg-1. Each intervention and control drink contains an addition of 2.0 g*l-1 sodium chloride, to closely match commercial sports drinks.

Study burden and risks

During the study no invasive measurements take place. Participants are asked to partake in high intensity running exercise sessions. It is not expected that the participants will consider the exercise sessions burdensome, because they are healthy, trained individuals with experience in running. Measurements include filling in a questionnaire concerning gastric distress, collecting breath samples, and blood samples (by fingerpricking). The provided CHO beverages are derived from natural starches and are not related to any adverse effect. Similar LOGP*s (Vitargo® S2, Cluster Dextrin®) have been administered in research trials and are commercially available, with no signs of negative consequences from use. Each participant will perform three 3 km-test sessions, and partake in a 10 km running event after which they will fill in a questionnaire concerning gastric distress. The total amount of time required for each participant is 255 minutes. The small subselection of participants who partake in the three gastric emptying testing sessions require an addition of 270 minutes in total. Participants will receive financial compensation. Aside from the running event, test procedures will be performed at the research facility of InnosportLab® Papendal, and the running track of Topsportcentrum Papendal, Arnhem.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy
Age 18-35
BMI 18.5-25
Intermediate level runners, train 2+ times/week for at least 30 min

Exclusion criteria

Disease/diabetes/frailty
Abuse of alcohol
Use of medication/drugs

Participating in another study intervention with effects on stomach function and/or endurance

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	30-01-2015
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL50919.081.14