Gastro-intestinal permeability and intense physical activity (GRINTA)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON40654

Source
ToetsingOnline

Brief title
Gastro-intestinal permeability and intense physical activity (GRINTA)

Condition

- Gastrointestinal conditions NEC

Synonym
gastro-intestinal permeabilty, gut barrier function, intestinal integrity

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,RAAKPRO;EHI (european hydration institute)

Intervention

Keyword: dehydration, gastro-intestinal permeability, inflammatory respons, physical activity

Outcome measures

Primary outcome

The main study parameters are the relative increase in intestinal permeability

(lactulose/rhamnose ratio) and plasma levels of glutamine and glutamine-derived

amino acids.

Secondary outcome

As secondary endpoints several markers of gastro-intestinal integrity and

inflammation are studied in blood, urine and saliva.

Study description

Background summary

It is widely accepted that moderate to intense continuous exercise increases intestinal permeability and leads to inflammatory responses. It is however unknown which intensity is necessary to induce these effects. In order to develop a commonly accepted and standardized physical stress model that can be applied to a broad population, the current study will compare three exercise protocols of different intensity. Furthermore, the role of proper hydration is not well documented to date. Therefore we also investigate the effect of hydration on intestinal permeability. We hypothesize that all exercise protocols will lead to an increase in intestinal permeability and inflammatory response. We further hypothesize that proper hydration can at least partially prevent the increase in intestinal permeability

Study objective

Primary Objective is to compare the effect of different exercise protocols on intestinal permeability and on plasma levels of glutamine and glutamine-derived amino acids, in healthy young men. A Secondary Objective is to assess the effect of different exercise protocols on immune - and gut barrier function markers and inflammation in plasma, urine and saliva, in order to establish

reference values of relevant biomarkers of intestinal permeability and inflammation in healthy young men. Fainally, we will establish the effect of proper hydration on gastro-intestinal permeability during intense exercise.

Study design

Randomized cross-over trial with 5 different conditions: rest; 60 minutes cycling at 70% of Wmax in euhydrated and dehydrated state; 60 minutes cycling at 50% of Wmax ; 60 min intermittent cycling at 85% and 55% of Wmax

Intervention

Ingestion of multi sugar and glutamine- alanine solutions to evaluate gut function. 5 different exercise conditions as described in study design

Study burden and risks

The risks for the subjects related to this study are minor. The exercise that has to be performed is moderate to intense and will be well tolerated within this group of participants, i.e. recreationally trained athletes. There is a small risk of bruising regarding the blood sampling procedures. The ingestion of the test products is not associated with an additional risk, and is well tolerated. There is no direct health benefit for the subjects, but the measurement of the Wmax and VO2max can be of interest for this group subjects. Next to this, subjects completing the study will receive a financial compensation of 75 ¤ for each experimental condition, i.e. 375 ¤ if they complete the study. Blood, urine, and saliva will be collected at several time points of the study. Next to this, the subjects have to adhere to specific guidelines the last days before and during each experimental test day and furthermore they will keep a log on diet, illness and exercise during the whole experiment.

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

• Male
• Generally healthy
• Recreational athlete with at least two years of cycling experience of at least twice a week
• 18-35 years old
• Meeting criteria of valid max-test
• Body mass index (BMI) 20-25 kg/m2
• Veins suitable for blood sampling at inspection

Exclusion criteria

• Known symptoms of immune diseases such as diabetes, celiac disease, gastric disease or cystic fibrosis
• Known symptoms of intestinal diseases such as Crohn*s disease, ulcerosis, irritable bowel syndrome or cystic fibrosis
• Smoking
• Use of hard drugs
• Use of specific medicines:
o Chronic use of NSAIDs: aspirin, ibuprofen, etc.
o Drugs for gastric and/or intestinal function
• Participation in other scientific studies
• Blood donation during the last six weeks prior to the start of the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-09-2014
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2014
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	NL49412.081.14