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The effect of different intensities of exercise on intestinal and immune function in healthy young men in the age of 18-35 years old

Submission date
20/03/2017

Recruitment status
No longer recruiting

Registration date
03/11/2017

Overall study status
Completed

Last Edited
03/01/2023

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Current nutrition research aims to improve the health state and prevent or delay disease. It is widely accepted that individual's health and well-being are strongly related to increased intestinal permeability. Improving intestinal permeability by means of food products could thus be a promising step in prevention and successful treatment of diseases related to Gastro-Intestinal (GI) permeability. However well-defined 'stress' models – in healthy subjects - with relevant biomarkers for GI permeability and intestinal function to evaluate nutritional effects, are not yet available. It is known that moderate to intense continuous exercise increases intestinal permeability and leads to inflammatory responses. Which intensity is necessary to induce these effects is, however, unknown. 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.

Who can participate?
Healthy moderately trained young men in the age of 18-35 years and a body mass of 20-25 kg /m2.

What does the study involve?
During preliminary testing the maximal aerobic capacity and maximal capacity (VO2max/Wmax) are determined. Subjects will start the study period in the rest condition and will cycle randomly allocated 4 exercise protocols: 1h at 70% Wmax; 1h at 70% Wmax in dehydrated condition; 1h at 50% Wmax and 1h alternating 55%/85% Wmax. Both 70% Wmax protocols, hydrated and dehydrated were allocated as a block. At the end of rest and the exercise subjects are asked to drink a multisugar and an amino acid solution. Before and after rest and exercise at several time point up to 24h, blood, urine and saliva samples are taken for intestinal function and immune markers. Blood samples are also taken halfway exercise. Subjects are asked to keep logs on training, illness and dietary.

What are the possible benefits and risks of participating?
The intensity is well-tolerated in this group of moderately trained cyclists and they can benefit from the measurement of the Wmax and VO2max to improve and optimize their training program and progress. The health risks associated for the subjects are minor. They will have to perform moderately to intense exercise which may result in fatigue, and can give some muscle soreness afterwards.

Where is the study run from?
The GRINTA! study takes place at the exercise lab of Wageningen University & Research Centre in Wageningen.

When is the study starting and how long is it expected to run for?
September 2014 to December 2014

Who is funding the study?
Netherlands Organisation for Scientific Research (Netherlands)

Who is the main contact?
1. Shirley Kartaram MSc shirley.kartaram@hu.nl
2. Raymond Pieters PhD raymond.pieters@hu.nl

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL 49412.081.14

Study information

Scientific Title

The effect of different intensities of exercise on biomarkers of GastRo-INTestinal Activity and immune function in healthy young men

Acronym
GRINTA!

Study objectives
The aims of this study are:
1. 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
2. To assess the effect of different exercise protocols on immune - and gut barrier function markers and inflammation in plasma, urine and saliva
3. To establish the effect of proper hydration on gastro-intestinal permeability during intense exercise

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee Wageningen University, 17/06/2014, ref:14/16

Study design
Single-centre randomized coss over design

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Gastro-intestinal function and immune response

Interventions
Fifteen healthy young men (20-35 yrs, VO2 max 56.9 ± 3.9 ml. kg-1 min-1) performed in a cross-over design five experimental protocols of one hour with different intensity and/or hydration status: 1) rest (group 1), 2) and 3) 70% Wmax respectively euhydrated (group 2) and dehydrated (group 3), 4) 50% Wmax (group 4) and, 5) intermittent 85/55% Wmax in blocks of 2 min (group 5). The wash out period between two experimental protocols was one week. Each subject

started with rest (group 1). After one week wash out each subject performed on individual base a randomly assigned exercise protocol (groups 2-5). The 70% Wmax hydrated and dehydrated conditions were randomized as a block.

At the end of rest and the exercise subjects are asked to drink a multisugar and an amino acid solution. Before and after rest and exercise at several time point up to 24h, blood, urine and saliva samples are taken for intestinal function and immune markers. Blood samples are also taken halfway exercise. Subjects are asked to keep logs on training, illness and dietary.

Intervention Type
Mixed

Primary outcome measure
1. Intestinal permeability (lactulose/rhamnose ratio) is measured using HPAEC (with pulsed electrochemical detection) at baseline, and each hour after rest and exercise up to 5 hours
2. Plasma levels of glutamine is measured using the UFLC (ultra fast liquid chromatography) at baseline, during (30 min) and after rest and exercise (60, 90, 120, 180, 360 min) up to 24 hours
3. Glutamine-derived amino acids are measured using the UFLC (ultra-fast liquid chromatography) at baseline, during (30 min) and after rest and exercise (60, 90, 120, 180, 360 min) up to 24 hours

Secondary outcome measures
Gastro-intestinal integrity and inflammation markers are measured using ELISA at baseline, during (30 min) and after rest and exercise (60, 90, 120, 180, 360 min) up to 24 hours.

Overall study start date
31/01/2014

Completion date
05/12/2014

Eligibility

Key inclusion criteria
1. Male
2. Generally healthy
3. Recreational athlete with at least two years of cycling experience of at least twice a week
4. 18-35 years old
5. Meeting criteria of valid max-test
6. Body mass index (BMI) 20-25 kg/m2
7. Veins suitable for blood sampling at inspection

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
Male

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
1. Known symptoms of immune diseases such as diabetes, celiac disease, gastric disease or cystic fibrosis
2. Known symptoms of intestinal diseases such as Crohn’s disease, ulcerosis, irritable bowel syndrome or cystic fibrosis
3. Smoking
4. Use of hard drugs
5. Use of specific medicines:
6. Chronic use of NSAIDs: aspirin, ibuprofen, etc.
7. Drugs for gastric and/or intestinal function
8. Participation in other scientific studies
9. Blood donation during the last six weeks prior to the start of the study

Date of first enrolment
01/09/2014

Date of final enrolment
01/11/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Wageningen University, Division Human Nutrition
Bomenweg 2
6307 HD Wageningen
Netherlands
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Sponsor information

Organisation
Utrecht University of Applied Sciences

Sponsor details
Heidelberglaan 7
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Sponsor type
University/education

Website
http://www.innovativetesting.nl/

ROR
https://ror.org/028z9kw20

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Scientific Research -Foundation Innovation Alliance

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2019	26/11/2020	Yes	No

Other publications	04/09/2020	03/01/2023	Yes	No