InTerlaboratory Evaluation of a GastroIntestinal Activity ErgoMeterTest in Non-intense Trained PersOns

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Primary Objective: To determine effects of less exercise,30 min 70% Wmax, on intestinal function and immune response in blood, urine and saliva.Secondary Objective: Interlaboratory evaluation of the ergometertest performed in Groningen and Utrecht...

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

Summary

ID

NL-OMON45536

Source
ToetsingOnline

Brief title
TEMPO! 2.0

Condition

- Gastrointestinal disorders

Synonym
gastrointestinal activity, gastrointestinal function

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Utrecht
Source(s) of monetary or material Support: SIA - RAAK PRO en NWO

Intervention

Keyword: Ergometertest, Gastro-intestinal activity, Healthy men, Interlaboratory evaluation

Outcome measures

Primary outcome

The relative changes in blood of iFABP (intestinal function), lymphocytes,

leukocytes, monocytes (immune response).

Secondary outcome

The relative changes in blood, urine and saliva of several markers of

intestinal function, immune responsiveness and general physiology: e.g.

cytokines, RNA-profiling of bloodcells, cortisol, aminoacids, sugars.

Study description

Background summary

General health seems strongly related to intestinal health and food intake. Food companies are interested in standardized models to test health-promoting effects of nutrition and related products (naturally occurring health-promoting products) to support health claims according the regulations of the European Food and Safety Authority (EFSA). For this human data are crucial if not obligatory. However, ergometer tests used to test effects of exercise have not yet been properly validated for nutritional studies, for instance with regard to lab transferability. In addition, a validated set of relevant e.g. function-related, biomarkers is not available, nor is clear how the extent of exercise intensity influences these biomarkers. Currently, a high intense exercise protocol of 70% Wmax is used, but this protocol is too intense for less fit individuals, e.g. elderly, obesity patients. A standardized bicycle ergometer test can be used to perform nutrition intervention studies with less-fit individuals.

Study objective

Primary Objective:
To determine effects of less exercise,30 min 70% Wmax, on intestinal function and immune response in blood, urine and saliva.

Secondary Objective:
Interlaboratory evaluation of the ergometertest performed in Groningen and Utrecht on parameters of intestinal function and immune response .

Study design

The study has a randomized cross-over design.
Each subject will complete 4 different experimental protocols, 1 at rest without exercise and 3 with exercise protocols:

1. 60 min at 70% of Wmax
2. 30 min at 70% of Wmax
3. 60 min at 50% of Wmax
4. 60 min rest (control)

Beforehand Wmax of the subjects will be determined by the VO2 max test.

Intervention

-Ingestion of a multisugar and glutamin/alanin solution

-Exercise with different load

Study burden and risks

The risks for the subjects related to this study are minor. Prior to the maximal capacity test, an ECG in rest will be taken to make sure that there are neither abnormalities or aberrant QT intervals. 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 cyclists. There is a small risk of bruising due to 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 (recreationally trained cyclists) but the values of Wmax and VO2max can be of interest for their trainingsscheme.

Contacts

Public
Hogeschool Utrecht

Heidelberglaan 7
Utrecht 3584 CS

NL
Scientific
Hogeschool Utrecht

Heidelberglaan 7
Utrecht 3584 CS
NL

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) 18.5-25 kg/m2
-Veins suitable for blood sampling at inspection

Exclusion criteria

-Diagnosed with an immune disease such as diabetes, coeliac disease, rheumatoid arthritis
-Diagnosed with an gastro-intestinal disease such as Crohn*s disease, colitis ulcerosa, irritable bowel syndrome
-abnormal ECG, e.g. an aberrant QT time
-Allergies
-Smoking
-Use of hard drugs
-Use of pre- and probiotics
-(Chronic) use of specific medicines:

*chronic use of NSAIDs: aspirin, ibuprofen, corticosteroids
*chronic use of antidepressiva, antacids (Rennie), benzodiazepines (Valium)
* drugs against abdominal pain and cramping (e.g.buscopan, imodium),
-Participation in other scientific studies within 1 month before the preliminary testing
-Blood donation six weeks prior to the start of the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2017
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	10-11-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-02-2017
Application type:	Amendment
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	NL58313.081.16