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

Published: 21-04-2016
Last updated: 17-04-2024

The primary objective is to evaluate the lab transferability of the exercise model as used in the GRINTA! study. This will be achieved by comparing the effect of exercise on biomarkers in blood, urine and saliva in two different laboratories. These...

| | |
|---|---|
| **Ethical review** | Not approved |
| **Status** | Will not start |
| **Health condition type** | Gastrointestinal inflammatory conditions |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON43135

**Source**
ToetsingOnline

**Brief title**
TEMPO!

### Condition

- Gastrointestinal inflammatory conditions

**Synonym**
gastrointestinal activity, intestinal barrier function

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** Bicycle Ergometer test, Gastrointestinal activiteit, Interlab evaluation, physical activity

## Outcome measures

### Primary outcome

The main study parameters are the relative changes in blood, urine and saliva of markers of intestinal barrier function (iFABP, lactulose/rhamnose ratio, zonulin), immune responsiveness (e.g. leukocytes) and of markers reflecting general physiological changes (e.g. cortisol). These parameters were most clearly affected in the study GRINTA!. As a new parameter we include RNA-profiling of blood cells, as indication of functional alterations in leukocytes.

### Secondary outcome

The relative changes in blood, urine and saliva of markers of intestinal barrier function (iFABP, lactulose/rhamnose ratio, zonulin), immune responsiveness (e.g. leukocytes) and markers reflecting general physiological changes (e.g. cortisol) in an intermediate-intense (moderate) exercise.

# Study description

### Background summary

Ergometer tests are frequently used to evaluate health-promoting effects of nutritional concepts. This is based on the notion that intense exercise, as a stressor, modulates intestinal and immune responses. Notably, kinetic changes of parameters (biomarkers) of gastro-intestinal or immunological alterations may allow the assessment of an individual*s fitness to respond to any stressor, including infections or inflammatory diseases. However, ergometer tests have not yet been properly validated, 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.
Recently, we have finished the GRINTA! study, which was coded NL 49412.081.14 Gastro-intestinal permeability and intense physical activity. In this study, we have included three exercise protocols that differed in extent of intensity (60 min 70%, 50%, interval 55%/85% of individual Wmax). These protocols were compared with each other, and with a rest-protocol and a dehydration protocol. To reduce variation we only tested young and fit (but not excessively trained) male volunteers, that nevertheless could barely fulfill the toughest protocol (Wmax 70% with dehydration). Results of the GRINTA! study show clear kinetic changes in a range of gastro-intestinal (e.g. citrulline, iFABP), immunological (e.g. leukocytes, including NK, macrophages, neutrophils) and general (e.g. insuline, cortisol) parameters. In addition, we found that a number of parameters also changed in the non-intense protocol of 50% Wmax, and that most parameters were already changed after 30 minutes of the 70% Wmax protocol.

The aim of the RAAK-PRO Diagrams project is to standardize the bicycle ergometer test. Another important aim of the project is to adapt the test-protocol so that it can be used to perform nutrition intervention studies with less-fit individuals, e.g. obese T2D patients. Results of the GRINTA! are very promising with regard to both aims.
An important step in standardization of any given test-method is to assess its lab transferability and its interlaboratory variation. We therefore propose to perform the bicycle ergometer test in 2 independent laboratories. In these studies, we intend to also test a less intense exercise protocols (30 min 70% Wmax, 50% Wmax).
We hypothesize that performance of the exercise protocols of 70% and 50% Wmax on different locations will show comparable effects on immune response and intestinal barrier function. In order to develop a test that can be applied to a broad population, we further hypothesize that less intense exercise also sufficiently influence various biomarkers.

**Study objective**

The primary objective is to evaluate the lab transferability of the exercise model as used in the GRINTA! study. This will be achieved by comparing the effect of exercise on biomarkers in blood, urine and saliva in two different laboratories. These studies will be done in young male volunteers and biomarkers are selected based on the GRINTA! study. The secondary objective is to determine whether an intermediate-intense (moderate) exercise sufficiently affects the selected biomarkers.

**Study design**

Randomized cross-over trial with 4 different experimental exercise protocols:

1) rest, 2) 60 min cycling at 70% Wmax, 3) 30 min cycling at 70% Wmax and 4) 60 min cycling at 50% Wmax.

### Intervention

Ingestion of multi-sugar and glutamine- alanine solutions to evaluate intestinal barrier function in 4 different experimental protocols 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 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 but the measurement of Wmax and VO2max can be of interest for this group of recreationally trained cyclists. Next to this, subjects will receive a financial compensation of ¤75,- for each experimental condition, i.e. ¤300,- if they complete the study. Blood, urine, and saliva will be collected at several time points of the study to establish kinetics of changes, which means that subjects have to be in the lab for 6 hrs and have to come back to the lab at 24 hrs after start of the cycling test. Next to this, the subjects have to adhere to specific guidelines the last days before and during each test day and furthermore they will have to keep a log on diet, illness and exercise during the whole study period.

## 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) 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
-Known symptoms of intestinal diseases such as Crohn*s disease, colitis ulcerosa, irritable bowel syndrome fibrosis
-Smoking
-Use of hard drugs
--Chronic use of NSAIDs: aspirin, ibuprofen, etc.
-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: | Will not start |
| Enrollment: | 16 |
| Type: | Anticipated |

## Ethics review

Not approved

| | |
|---|---|
| Date: | 21-04-2016 |
| 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 | NL56976.081.16 |