Can paracetamol alter thermoregulatory responses to exercise in healthy volunteers?

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The primary objective of the study is to examine the changes in core body temperature during a 60 minute cycling exercise bout at 85% of maximum predicted heart rate using double blind placebo or paracetamol in a group of healthy young subjects.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36074

Source
ToetsingOnline

Brief title
Paractamol and exercise

Condition

- Other condition

Synonym
hyperthermia

Health condition

hyperthermie (inspanningsgerelateerd)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: core body temperature, exercise, set point, thermoregulation

Outcome measures

Primary outcome

1. Core body temperature (continuous)

2. Plasma levels of pyrogens (IL-1, IL-6, TNF en IFNg)

Secondary outcome

n/a

Study description

Background summary

Exercise represents a strong stimulus for heat production in humans. Although heat dissipating mechanisms are activated rapidly after the onset of exercise and the subsequent rise in core body temperature, a strong increase in core body temperature can be observed in healthy subjects when performing exercise. Whilst resting core body temperature is well regulated between 36.5-37.5 °C, exercise can, dependent on various factors (duration, type and intensity of exercise) and external factors (air temperature, humidity, clothing), increase core body temperature up to 41 °C. Recent studies have demonstrated that acute exercise is associated with the production of pyrogens, such as interleukin-1 and -6. These pyrogens may contribute to the increase in core body temperature, providing evidence against the widely adopted believe that the increase in core body temperature during exercise is fully explained by heat accumulation due to a imbalance between heat production and heat dissipation.

Study objective

The primary objective of the study is to examine the changes in core body temperature during a 60 minute cycling exercise bout at 85% of maximum predicted heart rate using double blind placebo or paracetamol in a group of

healthy young subjects.

Study design

single centre, pilot study

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Submaximal bicycle exercise tests are safe in healthy volunteers without hypertension, normal ECG and without signs of cardiovascular disease. Also administration of paracetamol is safe, whilst this commonly used drug is not associated with important side effects or complications.

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

• Age : 18-45 years
• Willing to sign informed consent
• Healthy

Exclusion criteria

- hypersensitivity or idiosyncratic reaction to paracetamol.
- pregnant or lactating women.
- hepatic and/or renal impairment from participation.
- Because of potential interaction with other medication, we will exclude subjects with cholestyramine (which reduced the absorption speed of paracetamol), metoclopramide or domperidone (which speed of absorption of paracetamol is increased), warfarin (increased risk of bleeding) or chloramphenicol (increased plasma levels of chloramphenicol).
- obstructive disease of the gastro-intestinal tract (including diverticulitis and inflammatory bowel disease or previous gastrointestinal surgery, except cholecystectomy and appendectomy)
- subjects that will undergo a MRI-scan within 2 days after one of the testing days
- subjects with a cardiac pacemaker or other implanted electromedical devices
- As subjects will be performing a submaximal cycling test, we will also exclude:
• Hypertension (systolic blood pressure > 140 mmHg or diastolic blood pressure > 90 mmHg)
• Any cardiovascular abnormality in past medical history, physical examination or ECG, including prolonged QTc interval.
• BMI>=30 kg/m2
• Inability to perform bicycle exercise
• The presence of an absolute or relative contra-indication for exercise testing

Study design

Design

Study type: Observational non invasive

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-05-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL36213.091.11