Effect of exercise on Haemostasis

Published: 10-04-2013
Last updated: 15-05-2024

Primary: 1. To determine what the effect of exercise on coagulation.2. Establish the changes in bloodcell counts as a result of exercise.3. What the effect of exercise is on the platelet function.4. To test the different effects of cycling and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON38959

Source
ToetsingOnline

Brief title
Exercise and Haemostasis

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Endofibrosis, vessel narrowing

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Blood Counts, - Coagulation, - Enodfibrosis, - Exercise, - Haemostasis

Outcome measures

Primary outcome

• Changes in hematological parameters between pre and post exercise

• Changes in coagulation between pre and post exercise.

• Pre and Post exercise changes in platelet function and activity.

• Difference between the effect, of cycling and running on the test parameters

Secondary outcome

n.v.t

Study description

Background summary

Endofibrosis is a disease that occurs in 15-20% of the professional cyclist.
It's characterized by fibrosis of the iliacal arterie, the consequence is a thickening of the artery vessel wall and narrowing of the intima. Which results in a reduced blood flow to the leg.
It's a irreversible disease which can only be treated with an operation. Although in 1/3 of all cases, the treatment does not result in a foreseen outcome.
So far it's still unknown what causes endofibrosis. A small pelvic angle, which arises during cycling because of the sitting position, and changes in blood flow are recommended as important determinants. Moreover it's known that exercise can activate the coagulation, which can have an effect on some celtypes in the vessel wall.

Study objective

Primary:
1. To determine what the effect of exercise on coagulation.
2. Establish the changes in bloodcell counts as a result of exercise.
3. What the effect of exercise is on the platelet function.
4. To test the different effects of cycling and running on the test parameters.

Secondary:
1. To determine the underlaying mechanism of possible changes in coagulation

and platelet function after exercise.
2. To investigate the relation between coagulation and endofibrosis in cycling.

Study design

10 o'clock in the morning, blood will be collected from the cyclists for determination of haemostatic and haemotological parameters. After a normal intensive training of 4 hours, blood will be collected.
The runners will undergo the same protocol, only the training for the runners will be 1.5 hours

Intervention

The training for the cyclists will be 4 hour training in the Ardennes, with intensive moments on the hills. For the group runners the training will be 1.5 hour training on 80-85% of maximal heart frequency.
For both groups blood will be collected right before and after exercise.

Study burden and risks

The risks for the participants of the study are the same as at a normal vena punction, this is haematoma and bleeding at the spot of punction. Furthermore the training equal a normal training on for this group, so no higher risk is expected.

The burden and risks associated with participation are ethical responsible.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Population cyclists:
- minimal 18 years old and max 35 years old
- mentally capable
- train 3 times a week or more at the level of nation competition or higher;Population runners:
- minimal 18 years old and maximal 35.
- mentally capable
- train 3 times a week or more.

Exclusion criteria

- diagnosed with coagulation or platelet function disorder
- uses medication against coagulation or platelets
- vascular surgery in the past 6 months
- BMI >30
- using of doping
- pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-04-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20436
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	3846

Register	ID
CCMO	NL42855.068.12
OMON	NL-OMON20436