Invloed van inspanning door middel van wielrennen op het haemostatisch profiel.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20436

Source
NTR

Health condition

Exercise, coagulation, platelet reactivity, thrombin generation, endofibrosis, cycling

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Laboratory for Clinical Thrombosis and Haemostasis, Department of Internal Medicine,  Cardiovascular Research Institute Maastricht, Maastricht University Medical Center

Intervention

Outcome measures

Primary outcome

Expecting to show increased coagulation activity by increased TAT levels, supported by decreased Coagulation Time (CT) and enhanced Maximal clotting formation (MCF) by Rotem and enhanced thrombin generation through CAT assay. Increased fibrinolytic activity is expected by increased tPA and D-Dimer levels. Coagulation activation via the intrinsic pathway can be showed by enhanced thrombin generation in Active Side Inhibitor factor Seven (ASIS) assay. Increased platelet reactivity is expected by multiplate accompanied by a

increase in platelet count. Moreover we expect increase vWf levels, due to endothelial dysfunction.

Secondary outcome

Secondary outcomes can be a change in Hematocrit and Haemoglobin, due to plasma volume changes.

Moreover, outcomes can be that cycling exercise induces a internal haemostatic profile that can contribute to pathofysiological disease which are very common in cycling, endofibrose of the iliacal artery. Characterized by subendothelial fibrotic tissue formation. Protease Activated Receptors are known that they can induce fibrotic tissue formation and can be activated by coagulation factors (FXa and Thrombin).

Study description

Background summary

Although a clear association between exercise and activation of coagulation has been demonstrated, evidence is fragmented and the trigger remains unknown. Given the protease activated receptor (PAR) activation by coagulation proteases and the subsequent cellular effects such as inflammation, migration and apoptosis, haemostatic changes during exercise may contribute to the development of endofibrosis in cyclists. This pathology is characterized by intimal thickening of the iliacal artery, with reduced blood flow as a consequence.

Study objective

Does cycling exercise induce increased coagulation activity through contact activation?

Study design

March 2013: Start of study.

Every 2 weeks a group of 5 cyclists and controle groupe will be tested. So 20 cyclists and 20 controle group members will be tested within 2 months.

Intervention

Blood will be collected before and after long-term strenuous exercise. Coagulation profile will be measured bij Thrombin Generation (CAT), Rotem;Natem and by measuring Thrombin-Antithrombin complex , Coagulation Factor XIa (FXIa), tissue Plasminogen Activator (tPA), D-

Dimer and von Willebrand Factor (vWf). Platelet reactivity will be assesed by Multiplate. Blood cell counts are determined for testing the full blood cell count profile by: Hematocrit, Haemoglobin, platelets, cortisol and leukocytes (differentiation).

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Eligibility criteria

Inclusion criteria

1. Minimal 18 years old;

2. Trains more than 3 times a week;

3. Mentally competent.

Exclusion criteria

1. Diagnosed with coagulation or platelet disorder;

2. Using medication against coagulation or platelet function;

3. Vascular operation within 6 months before the research;

4. BMI > 30;

5. Prestation influencing drugs;

6. Pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2013
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 38959
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3676
NTR-old	NTR3846
CCMO	NL42855.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38959

Study results

Summary results
N/A