The effect of strenuous exercise on coagulation: Hemostatic behaviour before and after Amstel Gold Race

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The objective is to investigate the effect of strenuous exercise (participation to the Amstel Gold Race) on coagulation and haemostatic parameters.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON40454

Source
ToetsingOnline

Brief title
The Amstel Gold Race study

Condition

- Haematological disorders NEC

Synonym
hypercoagulability, thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,medegesponsord door Synapse bv,Synapse bv

Intervention

Keyword: exercise, haemostasis, thrombin generation

Outcome measures

Primary outcome

Whole blood (WB) will be used for WB-TG, ROTEM, haematocrit, haemoglobin, and platelet count testing. Plasma will be stored for plasma-TG, PT, APTT, dRVVT-X, measurement of the factor concentrations (II, V, VII, VIII, IX, X, XI, XII, fibrinogen, protein C/S), ADAMTS-13, VWF (antigen/activity), D-dimers and a fibrinolysis assay. Additionally, we will also look at the heart frequency, blood pressure and oxygen levels, cardiac biomarkers and a questionnaire on the trainingsstatus of the participants.

Secondary outcome

Not applicable.

Study description

Background summary

Many studies have shown that vigorous exercise increases the risk of developing vascular thrombotic events and can result in sudden death during or immediately after exercise. The outcome of these studies is biased by several confounding variables: subjects, type of exercise, duration, intensity and especially the method used for the evaluation of the hemostatic capacity. The goal of our study is to investigate the effect of strenuous exercise with the Calibrated Automated Thrombogram (CAT) assay, which is an established tool in detecting hyper- and hypocoagulabilty conditions. We modified the CAT assay to make it also feasible to measure TG in whole blood (WB-CAT), not only to go one step closer to physiology since all the blood cells are present, but also to avoid the centrifugation step.
With our study we would like to see whether the other blood cells also play a role in the increase in TG.

Study objective

The objective is to investigate the effect of strenuous exercise (participation to the Amstel Gold Race) on coagulation and haemostatic parameters.

Study design

Healthy participants of the Amstel Gold Race for non-professionals will be asked to join our study. Blood samples will be taken via venipuncture (23 ml) and fingerprick (15 µl) before and after the Race.

Study burden and risks

23ml of blood will be taken twice from each subject, one sample will be taken before the Amstel Gold Race and one sample will be taken after the Race. Blood sampling will be done by experienced medical researchers and will only cause short bruising. There is no direct benefit for the patients and the patients do not have to come back for the purpose of our study.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Oxfordlaan 70
Maastricht 6229EV
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Oxfordlaan 70
Maastricht 6229EV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Healthy subjects not taking any medication interfering with coagulation that are willing to donate 23 ml of blood via venipuncture and a capillary blood drop via fingerpuncture before and after the Amstel Gold Race.
• Between 18 and 50 years of age. We take 50 year as a maximal age to prevent any co-morbidity that could have an influence on coagulation (like diabetes, atherosclerosis, peripheral arterial disease, *).
• Etnicity will not be included as an inclusion or exclusion criteria.

Exclusion criteria

• Subjects taking any medication interfering with coagulation.
• Subjects having a cardiovascular disease or any other serious medical problem.
• Subjects below 18 years or above 50 years of age.
• Subjects that smoke.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2014
Enrollment:	96

Type:	Actual

Ethics review

Approved WMO Date:	27-02-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-04-2014
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02048462
CCMO	NL47367.068.13