

BLO2D Unlimited

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29315

Source

NTR

Health condition

High altitude

Physical exercise

Blood coagulation

Thrombosis

Extreme hoogte

Lichamelijke spanning

Bloedstolling

Trombose

Sponsors and support

Primary sponsor: Maastricht University Medical Center

Synapse Research Institute

Source(s) of monetary or material Support: Synapse Research Institute

Intervention

Outcome measures

Primary outcome

Trombin generation

Secondary outcome

- Plasmin generation
- Platelet function test
- Thromboelastometry
- Blood count
- Fibrinolysis (clot lysis time)
- Coagulation factor analysis: von Willebrand factor (vWF), factor 8 (FVIII), D-dimers
- Biochemical markers: lactate, creatinine, urea, albumin

Other outcome parameters:

- Age
- Vital signs (heart rate, blood pressure and SpO2)
- Questionnaire (Lake Louise AMS)

Study description

Background summary

Strenuous exercise activates blood coagulation, mostly due to elevated platelet count, platelet hyperreactivity, increased thrombin generation and increased activity of several coagulation factors, especially factor 8 (FVIII) and von Willebrand factor (vWF).

Mountaineering also appears to pose a risk for developing thrombosis. Healthy lowlanders moving to high altitude for a mean duration of 10 months were found to have a 30 times increased risk of developing a venous thromboembolism (VTE). Similarly, healthy soldiers stationed at high altitude were characterized by an almost 25-fold increased risk of developing deep calf vein thrombosis. Mountaineering usually involves repeated strenuous

exercise, when walking, climbing, skiing or cycling. Because hypoxia and exercise both cause procoagulant changes, one might expect that exercise will amplify the altitude-induced hypercoagulability.

From 2 recent studies (Mont Blanc 1 and 2 studies), we concluded that hypoxia induces prothrombotic changes in blood. We have also found that strenuous exercise leads to prothrombotic changes (Red Meets Gold study), but these appear to be attenuated during repeated exercise (unpublished work). Mountaineering combines both hypoxia and repeated strenuous exercise.

In this study we aim to investigate the effect of 3x repeated strenuous exercise at high altitude on blood, using advanced techniques for studying thrombin generation, platelet function and fibrinolysis. It is hypothesized that high altitude and strenuous exercise cause increased thrombin generation, but that this effect will be attenuated during prolonged exposure and repeated exercise.

Study objective

It is hypothesized that strenuous exercise at high altitude causes increased thrombin generation, but that this effect will be attenuated during prolonged exposure and repeated exercise.

Study design

N/A

Intervention

- Strenuous physical exercise (heart rate reserve 60-85%) during 2 hours, once at sea level (baseline) and repeated 3x at high altitude (3,883 m above sea level)
- Venipuncture just before and immediately after exercise (8x27 ml)

Contacts

Public

Maastricht University Medical Center, department of Anesthesiology and Pain Therapy;

C.H. Kicken
Maastricht
The Netherlands

Scientific

Maastricht University Medical Center, department of Anesthesiology and Pain Therapy;

C.H. Kicken

Maastricht

The Netherlands

Eligibility criteria

Inclusion criteria

- Healthy male volunteer
- Age between 18 and 50 years old

Exclusion criteria

- Previous history of cardiovascular disease, pulmonary disease, bleeding disorder or venous thromboembolism
- Medication interfering with blood coagulation (low molecular weight heparins, vitamin K antagonists, direct oral anticoagulants, non-steroidal anti-inflammatory drugs)
- Impaired mobility
- Active smoking
- Not passing medical assessment
- Disapproval of contacting general practitioner in case of abnormalities found during medical assessment or during the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2017
Enrollment:	6
Type:	Actual

Ethics review

Positive opinion	
Date:	05-03-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45638
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6148
NTR-old	NTR6279
CCMO	NL61217.068.17
OMON	NL-OMON45638

Study results