

The effect of exercise at high altitude on thrombin generation in whole blood and ATP release from platelets

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The objective of our study is to investigate the effect of exercise on thrombin generation in WB and on ATP release from platelets under hypoxic conditions at high altitude.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON49175

Source

ToetsingOnline

Brief title

Beyond BLO2D unlimited

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym

hypercoagulability - coagulation disorder

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W, Synapse Research Institute

Intervention

Keyword: ATP release, Exercise, Hypoxia, Thrombin generation

Outcome measures

Primary outcome

ATP release from platelets and thrombin generation in whole blood.

Secondary outcome

Thrombin generation in platelet poor plasma, platelet function test in whole blood, blood count and vital signs (oxygen saturation, heart rate and blood pressure).

Study description

Background summary

Hypoxia is known to be associated with thrombosis and plays an important role in many pathologies, e.g. Chronic Obstructive Pulmonary Disease and obstructive sleep apnea syndrome, in which oxygen desaturation seems to be one of the mediators in the connection with hypercoagulability. In order to study the influence of hypoxia on haemostasis, several studies have been done in healthy individuals being exposed to lower oxygen pressure by either going to high altitude or by inducing hypobaric hypoxia. Our group also investigated the effect of hypoxia on haemostasis and from these studies, we could conclude that hypoxia caused an increase in thrombin generation when performed in whole blood, but not in plasma, as well as an increase in coagulation factor VIII and von Willebrand factor due to exercise. As we did not observe an increase in platelet activation, we hypothesize that the hypercoagulability caused by hypoxic conditions (either due to high altitude or due to hypobaric hypoxia), is balanced by the human body by decreasing platelet activation.

Study objective

The objective of our study is to investigate the effect of exercise on thrombin generation in WB and on ATP release from platelets under hypoxic conditions at high altitude.

Study design

It is an unblinded cross-over interventional study. In total blood will be taken 4 times: 1. Maastricht (50m); 2. Furi (1832m); 3. Klein Matterhorn after going up passively (3883m); 4. Klein Matterhorn after going up actively (3883m). Every participant is its own control.

Intervention

The volunteers in our study will experience oxygen deprivation by up the mountain. This will be done passively and actively by walking up the mountain. Blood samples will be taken via venipuncture.

Study burden and risks

All volunteers will undergo medical test prior to the start of the study, to ensure that all participants are physically healthy. Four blood samples of 27 ml each will be drawn, which poses a risk of developing a local bruise or hematoma. Mountaineering poses a risk of developing acute mountain sickness (AMS), a clinical syndrome ranging from dizziness, nausea and lethargy to ataxia, vomiting and unconsciousness. All participants will be screened daily for symptoms of AMS by using the Lake Louise AMS questionnaire. Participants will be accompanied by the principal investigator at high altitude and emergency care will be delivered if necessary. An experienced mountain guide will be present. Participants will be escorted back to 1000m if AMS symptoms are present.

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

- * Healthy
- * 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 (see section 3)
- * Disapproval of contacting general practitioner in case of abnormalities found during medical assessment or during the study

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 18-08-2021
Enrollment: 12
Type: Actual

Ethics review

Approved WMO
Date: 22-08-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL70436.068.19