Mont Blanc 2: Where Red And White Meet Again

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

Summary

ID

NL-OMON44545

Source
ToetsingOnline

Brief title
The Mont Blanc study 2

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

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,Synapse Research Institute

Intervention

Keyword: Coagulation, Hypoxia, Thrombosis

Outcome measures

Primary outcome

Whole blood will be used for measuring thrombin generation, platelet function test, measuring phospholipid exposition on the cellular membranes and for a whole blood count (Hb, Ht, number of red blood cells, number of leucocytes, number of platelets). The whole blood thrombin generation samples will be fixated for studying blood cell morphology using scanning electron microscopy. Plasma will be used for measuring thrombin generation, routine coagulation tests and for quantifying microparticles.

Secondary outcome

N.A.

Study description

Background summary

Hypoxia is an important aspect of several diseases, such as COPD and OSAS. These diseases are also characterised by an increased risk of developing thrombosis, for instance COPD patients admitted to the hospital have a 25% chance of developing a pulmonary embolism. The mechanism behind this is still unknown, but it has been suggested that immobilisation, inflammation and hypoxia play a major role.
Recently our study group investigated the effect of hypoxia on blood coagulation, by ascending from sea level to 4,000 m with two groups of healthy participants: one actively climbing group and one passively ascending group (using cable cars). By measuring thrombin generation, we found that hypoxia leads to an elevation of thrombin generation in whole blood, but not in plasma. Because of this discrepancy, is is thought that the cellular part of the blood is influenced by the hypoxia and may be responsible for the increased risk of

thrombosis.

Study objective

We aim to investiga the effect of hypoxia on blood coagulation and the blood cells, particularly on blood cell activation, microparticle release and expression of anionic phospholipids on the cell membrane. We also want to investigate whether the effects of a stay at high altitude (hypobaria) are compareble to a stay in a hypoxic chamber, where air pressure is not decreased (normobaria).

Study design

Our study consists of two parts:

Part A (Expedition): hypoxia will be induced by ascending passively from sea level to 4,000 m, over a period of 7 days. During this expedition we will focus on the effect of hypoxia on blood cells and blood coagulation. These data will be correlated to our previous expedition.

Part B (Hypoxia Chamber): hypoxia will be induced by a 10 hour stay in a normobaric hypoxic chamber, in which the oxygen level is adapted to resemble 3,000m above sea level. Healthy participats will stay twice in the room: once exposed to room air (single blinded control), and once exposed to the hypoxia.

Intervention

N.A.

Study burden and risks

Blood samples will be drawn by venipuncture by experienced scientists. Venipuncture can lead to a bruise.
During the Expedition a qualified medical doctor will join the group and will monitor the health of all participants by regular measurments of vital functions and by drawing a questionnaire about mountain sickness. Also the group will be accompanied by an experienced qualified mountain guide who is aquanted with the Mont Blanc area.
If a volunteer experiences any sign of mountain sickness, the volunteer will be escorted back to the base camp at 1.000m immediately and receive immediate care, or be brought back to The Netherlands. No unneccessary risks will be taken.

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 subjects (without any morbidity and witbout obvious signs of illness, not taking any medication interfering with coagulation), willing to participate in bot parts of our study
All healthy volunteers will undergo a physical check-up by a medical doctor. During this check-up, the medical doctor will look at the ECG, measure blood pressure, heart rate and blood oxygen level.
Subjects must be between 18 and 50 years of age. This maximum age is taken to prevent comorbodities that may influence coagulation (such as diabates, atherosclerosis, peripheral arterial disease).

Exclusion criteria

Use of medication interfering with blood coagulation (such as vitamin K antagonists, new oral anticoagulants, low molecular weight heparins).
Presence of cardiovascular disease of any other serious comorbidity.
Age below 18 of above 50 years old.
Not passing physical check-up.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2015
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO Date:	06-10-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-05-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-03-2016

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
CCMO	NL49890.068.14
Other	NTR4806 (trialregister.nl)

Study results

Date completed:	20-03-2016
Results posted:	25-03-2016
Actual enrolment:	37

First publication
07-12-2015