The Mont Blanc study 2

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23647

Source
NTR

Health condition

hypoxia altitude thrombosis thrombin generation

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University
Synapse bv

Intervention

Outcome measures

Primary outcome

Thrombin generation will be done in whole blood and plasma with and without the addition of exogenous thrombomodulin. The parameters we will study at are: the peak height, ETP, lagtime, time-to-peak and velocity index.

Samples after TG will be fixated for scanning electron microscopy (SEM) for cell morphology. Facs experiments will be performed for PS-exposure and platelet reactivity.

Flow experiments for thrombus formation analysis with microfluidic chips.

Secondary outcome

• Routine coagulation tests (APTT, PT, INR, platelet count, haematocrit)

• Measurements of coagulations factor levels (II, V, VII, VIII, IX, X, protein S and C, hemoglobin)

• Blood pressure, heart frequency, blood oxygen level.

Study description

Study objective

We hypothesize that the interaction between blood cells, platelets, red blood cells or monocytes and the plasma compartment is responsible for the increase in thrombotic risk. Therefore, we aim to investigate the effect of hypoxia on the blood cells, how/why they get activated, develop microparticles, and express anionic phospholipids on their outer membrane. In order to achieve this we also need to establish whether the results of a stay in the hypoxic chamber are comparable to a stay at high altitude, regardless of the difference in barometric pressure. We do not expect differences in physical activity or gender during the stay in a hypoxic chamber, but we need to exclude this. Last but not least, we would like to investigate whether reoxygenation also plays a role in the development of thrombosis after hypoxia.

Intervention

Induction of hypoxia by either going on altitude or by a stay in a low oxygen chamber.

Contacts

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Eligibility criteria

Inclusion criteria

• Healthy subjects (not having any morbidity and without obvious sign of illness and not taking any medication interfering with coagulation) willing to participate to both parts of our study.

• All healthy volunteers will undergo a physical check-up by an authorized medical doctor. During this physical check-up the doctor will look at the ECG, the blood pressure, the heart rate and blood oxygen level.

• Between 18 and 50 years of age. We take 50 years as a maximal age to prevent any co-morbidity that could have an influence on coagulation (like diabetes, atherosclerosis, peripheral arterial disease, ...).

Exclusion criteria

• Subjects taking any medication interfering with coagulation.

• Subjects having a cardiovascular disease or any other serious medical problem.

• Subjects below 18 or above 50 years of age.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2014
Enrollment:	28
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4637
NTR-old	NTR4806
Other	: METC143032

Study results