# BLO2D Unlimited

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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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON29315

**Bron**
Nationaal Trial Register

**Aandoening**

High altitude

Physical exercise

Blood coagulation

Thrombosis

Extreme hoogte
Lichamelijke ispanning
Bloedstolling
Trombose

### Ondersteuning

**Primaire sponsor:** Maastricht University Medical Center
Synapse Research Institute
**Overige ondersteuning:** Synapse Research Institute

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Trombin generation

# Toelichting onderzoek

### Achtergrond van het onderzoek

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leads to prothrombotic changes (Red Meets Gold study), but these appear to be attenuated during repeated exercise (unpublished work).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.

### Doel van het onderzoek

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.

**Onderzoeksopzet**

N/A

**Onderzoeksproduct en/of interventie**

- 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)

# Contactpersonen

## Publiek

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

C.H. Kicken
Maastricht
The Netherlands

## Wetenschappelijk

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

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Maastricht
The Netherlands

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Healthy male volunteer

- Age between 18 and 50 years old

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 17-06-2017 |
| Aantal proefpersonen: | 6 |
| Type: | Werkelijke startdatum |

## Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 05-03-2017 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45638
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten