The effects of cooling on the human inflammatory response

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24451

Source
Nationaal Trial Register

Brief title
ESCIMO

Health condition

Cooling, fever control, endotoxemia, inflammation, healthy volunteers

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Host immune response: Il-6 (primary outcome), but also Full blood count, leukocyte differentiation, C-reactive protein (CRP)
Other pro- and anti-inflammatory cytokines by enzyme-linked immunosorbent assay (ELISA), markers of endothelial condition (von willebrand factor(vWF), syndecan-1, thrombomodulin by ELISA. Expression of granulocyte activation and adhesion molecules by flow cytometry.

HLA-DR expression will aslo be measured with flow cytometry. Urine levels of catecholamines will be measured using ELISA. Whole blood ex-vivo stimulation with LPS and LTA

Secondary outcome

Coagulation processes: Activated partial thromboplastin time (APTT), (partial thromboplastin time) PTT, D-Dimer, rotational thromboelastometry (ROTEM).
By ELISA: F1+2, thrombin generation, tissue factor, tissue factor pathway inhibitor, protein-C levels, antithrombin, Proteinase-activated receptor(PAR)-1, plasminogen activator inhibitor(PAI)-1.

Tissue perfusion and oxygenation: Nexfin will be used to measure cardiac output.

SDF will be used to visualize and examine the microcirculation in real time.
NIRS will be used to assess tissue oxygenation.

Study description

Study objective

We hypothesize that cooling reduces endotoxemia induced inflammation and does not cause immunosuppression.

Study design

T=0, T=1, T=3, T=6, T=8

Intervention

Group 1: LPS + external cooling to 36¡ãC from T = 0 hours after LPS infusion

Group 2: LPS

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy male volunteer

2. Age ¡Ý 18 years <35 years

3. BMI between 20 and 25 kg/m2

Exclusion criteria

1. No informed consent

2. Any abnormal test result during the screening prior to inclusion of the study (medical history, physical examination, ECG, blood examination).

3. History of drug abuse

4. Any present medication use on prescription

5. Participation in any other medical drug study < 3 months

6. Participation in previous volunteer studies using LPS

7. History of an allergic reaction to opiates

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-05-2017
Enrollment:	12
Type:	Unknown

Ethics review

Positive opinion

Date:	06-04-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45163
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6203
NTR-old	NTR6367
CCMO	NL53460.018.15
OMON	NL-OMON45163

Study results