Concentration/meditation as a novel means to limit inflammation: a randomized controlled pilot study

Published: 19-10-2012
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON39551

Source
ToetsingOnline

Brief title
Effects of concentration/meditation on inflammation

Condition

- Autoimmune disorders

Synonym
Auto-immune diseases, reumathoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Reumafonds (seredipity budget);geen integrale financiering

Intervention

Keyword: concentration, iceman, inflammation, meditation

Outcome measures

Primary outcome

The main study endpoint is the difference in concentration of circulating TNF-α following LPS administration between the concentration/meditation group and the control group.

Secondary outcome

Secondary study parameters include other circulating cytokines (IL-6, IL-10 and IL1RA), body temperature, hemodynamics, cortisol, catecholamines, heart rate variability, and blood gas parameters.

Study description

Background summary

Auto-immune diseases are characterized by an inappropriate inflammatory response against tissues in the body and represent a major health care burden. Pro-inflammatory cytokines such as TNF-α, IL-6 and IL-1β play a central role in the pathophysiology of many auto-immune diseases. Innovative therapies aimed at limiting pro-inflammatory cytokine production in a more physiological manner are warranted. In previous research conducted in an individual known as *the iceman*, we found that, through a autodidact concentration/meditation technique, he appears to mount a controlled stress response, characterized by activation of the sympathetic nervous system and enhanced production of cortisol, both of which are known to result in immunosuppression. In accordance, while practicing this concentration/meditation technique, the inflammatory response during human endotoxemia (lipopolysaccharide [LPS] administration) was remarkably low in this individual. Therefore, this technique could provide a novel means of controlling the inflammatory response. However, the aforementioned results were obtained in just one subject, and hence can not serve as scientific evidence for the effectiveness of the concentration/meditation technique. The iceman claims that he can teach this technique to other subjects within a relatively short time frame.

Therefore, in the present study we wish to investigate the effect of concentration/meditation on autonomic nervous system activity and the inflammatory response during experimental human endotoxemia in a controlled manner, by comparing a group of subjects that are trained by *the iceman* and practice the concentration/meditation technique with a group of subjects which do not.

Study objective

The main objective of the study is to determine the effect of practicing the iceman*s concentration/meditation technique on the inflammatory response during human endotoxemia (lipopolysaccharide [LPS] administration in healthy volunteers).

Secondary objectives are
1. To determine the effects of concentration/meditation on the stress response and autonomic nervous system activity.
2. To determine the effects of the concentration/meditation technique on blood gas parameters.

Study design

Parallel randomized controlled pilot study in healthy male volunteers during experimental endotoxemia.

Intervention

Concentration/meditation for 3 hours starting 30 minutes before LPS administration. To master the concentration/meditation technique, a group of subjects (concentration/meditation training group, n=18) will be trained by the iceman in the concentration/meditation technique. Of these 18 subjects, a group of 12 subjects will be randomly selected; these 12 subjects comprise the *concentration/meditation group*. 12 other subjects which are not trained comprise the *control group*. Subjects of both the concentration/meditation group and the control group (total n=24) participate in the human endotoxemia trial (administration of an intravenous bolus [2 ng/kg] of LPS derived from E coli O:113), during which the concentration/meditation group will practice the concentration/meditation technique.

Study burden and risks

All subjects will visit the hospital for a screening visit in which a medical interview and physical examination will be carried out (30 minutes). The concentration/meditation training group will be trained by the iceman and his team for approximately 10 days (including self study at home). The iceman and his team have trained over 500 subjects (including more than 30 patients with

varying illnesses), and no side effects have ever occurred. The control group will receive no training or self-study assignments. The subjects that participate in the human endotoxemia trial will be admitted to the hospital on the endotoxemia experiment day (10 hours). During the endotoxemia experiment day, volunteers will receive an arterial line that will be placed under local anaesthesia. Furthermore, a venous cannula will be placed for the administration of fluids and LPS. The administration of LPS induces flu-like symptoms for approximately 4-6 hrs. This model of systemic inflammation has been applied for many years in thousands of subjects in various research centres in the world. LPS administration is considered safe and no long-term effects have ever been documented. At the Radboud University Medical Centre, over 280 volunteers have received more than 350 injections of LPS. Therefore, there is sufficient experience with this model at this centre. In total, approximately 350 ml blood will be drawn during the study, which is comparable to previous human endotoxemia studies and has never resulted in adverse events. Subjects may not benefit directly from participation to the study, although mastering the iceman*s techniques is considered a benefit by many. A subject fee is provided.

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

- Age >=18 and <=35 yrs
- Male
- Healthy
- Travel insurance (for travel to Poland for the training in the concentration/meditation technique

Exclusion criteria

- Use of any medication
- Smoking
- Use of recreational drugs within 21 days prior to endotoxemia experiment day
- Use of caffeine or alcohol within 1 day prior to endotoxemia experiment day
- Previous participation in a trial where LPS was administered
- Surgery or trauma with significant blood loss or blood donation within 3 months prior to endotoxemia experiment day
- Participation in another clinical trial within 3 months prior to endotoxemia experiment day.
- History, signs, or symptoms of cardiovascular disease
- History of frequent vaso-vagal collapse or of orthostatic hypotension
- History of atrial or ventricular arrhythmia
- Hypertension (RR systolic >160 or RR diastolic >90)
- Hypotension (RR systolic <100 or RR diastolic <50)
- Conduction abnormalities on the ECG consisting of a 1st degree atrioventricular block or a complex bundle branch block
- Renal impairment: plasma creatinine >120 µmol/L
- Liver function abnormality: alkaline phosphatase >230 U/L and/or ALT >90 U/L
- History of asthma
- Obvious disease associated with immune deficiency.
- CRP >20 mg/L, WBC >12x109/L, or clinically significant acute illness, including infections, within 4 weeks before endotoxemia day

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	19-10-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-02-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
Other	Clinicaltrials.gov, registratienr volgt
EudraCT	EUCTR2012-004622-14-NL
CCMO	NL42337.091.12