Aeonose and Complex Regional Pain Syndrome

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The goal of the study is to investigate whether the Aeonose can detect a CRPS-specific pattern of volatile organic compounds in the exhaled air of patients with CRPS.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40997

Source
ToetsingOnline

Brief title
Aeonose and CRPS

Condition

- Other condition

Synonym
Complex Regional Pain Syndrome, posttraumatic dystrophy

Health condition

Pijn

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aeonose, Complex Regional Pain Syndrome (CRPS), Electronic Nose

Outcome measures

Primary outcome

Distribution of volatile organic compounds (VOC*s) in exhaled air.

Secondary outcome

n.a.

Study description

Background summary

CRPS
Complex Regional Pain Syndrome (CRPS) is a disabling neuropathic pain syndrome characterized by spontaneous or stimulus-evoked pain, oedema, vasomotor, and sudomotor abnormalities, motor dysfunction, and trophic changes, but with no clear evidence for peripheral nerve injury. Though varying suggestions have been made, such as inflammation, altered sympathetic activity, ischemia, and reperfusion injury and central sensitization, the underlying mechanism of CRPS is as yet unclear. Moreover, the therapeutic interventions for the management of this disease are both controversial and limited. These therapeutic strategies include pharmacologic pain relief, sympatholytic interventions, and rehabilitation.
Furthermore, to date there is no specific laboratory test for CRPS; diagnosis of the disease is based on clinical observations of signs and symptoms and on tests such as the WHO analgesic ladder, quantitative sensory testing (QST), autonomic testing that include quantitative sudomotor axon reflex test (QSART) for sweating abnormalities, the cold pressor test in conjunction with thermographic imaging to observe the vasoconstrictor response, and laser Doppler flowmetry to monitor background vasomotor control. Until a better understanding of mechanistic overtones helps to put in place mechanism-based therapeutic strategies, management will continue to be built around a rehabilitation model.

Aeonose
Pathological conditions often cause metabolic changes in the body resulting in measurable changes in the blood. At the lung surface, there is an intensive exchange of organic compounds between the blood and the air in the lungs. We

call them volatile organic compounds (VOC*s). Our human olfactory system is mostly unable to detect these components, sometimes however it can (e.g. acetone in diabetic patients).
Using exhaled air as potential diagnostic indicator is increasingly common. The electronic nose technology is a diagnostic test able to detect a pattern of volatile organic compounds (VOC*s) in exhaled air.
Basically, it consists of a number of metal-oxide sensors following a cyclic temperature profile. On the sensor surface, redox-reactions can take place changing the conductivity of the sensor. This conductivity change is measured at several positions within the temperature cycle and is dependent upon a.o. the volatiles present, reaction products, reaction dynamics, and temperature. The multi-way data generated are being compressed and consequently analysed using statistical techniques.
Electronic noses are already used for different medical purposes including the diagnostics of asthma, chronic obstructive pulmonary disease, urinary tract infection, wound infection, and even cancer. An electronic nose is also used for the laboratory-based identification of bacterial pathogens.

We expect the Aeonose is able to detect CRPS as well. The cells involved in inflammation might be detected in the exhaled air.

Study objective

The goal of the study is to investigate whether the Aeonose can detect a CRPS-specific pattern of volatile organic compounds in the exhaled air of patients with CRPS.

Study design

This study is a prospective investigator blinded observational study

Study burden and risks

Subjects will be asked to breath gently through the Aeonose for five minutes, with a little clamp attached to their nose. This might cause some slight discomfort. This feeling often passes when they breathe on for some time. When the discomfort becomes too much, the measurement will be ceased. Participation in the study is not associated with any further risk.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

A Diagnosis of CRPS, according to the Budapest Criteria for the diagnosis of CRPS.

Exclusion criteria

Age < 18 years
Drinking alcohol/coffee or smoking in the hour before the experiment
Such a severe disease the test cannot be done

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48206.078.14