Heart rate variability as a measure of pain intensity in healthy volunteers

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The objective of this study is to determine whether heart rate variability measures correlate with pain intensity measured by a visual analogue scale in healthy volunteers in whom pain is induced by local heat application.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33227

Source
ToetsingOnline

Brief title
Heart rate variability as a measure of pain intensity in healthy volunteers

Condition

- Other condition

Synonym
pain

Health condition

pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Heart rate variability, Pain measurement

Outcome measures

Primary outcome

The primary endpoint of the study will be the correlation between the change in pain intensity as measured by the visual analogue scale and as measured by heart rate variability.

Secondary outcome

1) whether there is a correlation between the response to pain using the visual analogue scale and the neuroticism subscale of the Eysenck Personality Questionnaire

2) whether there is a correlation between the response to pain using heart rate variability measures and the neuroticism subscale of the Eysenck Personality Questionnaire

3) the reproducibility of the correlation between the change in pain intensity and heart rate variability measures

Study description

Background summary

Pain is considered to be multifactorial. It consists of physical pain -somatic, visceral and/or neuropathic-, psychosocial, emotional and spiritual pain. When measuring pain intensity, the pain experience of a patient is measured. This is

subjective as only a patient can describe how he experiences his pain. In the clinic, the visual analogue scale (VAS) is the standard tool to measure pain intensity. This is a scale ranging from 0 (no pain) to 10 (the worst pain imaginable). The patient can indicate his pain intensity at a specific moment. It is an easy tool to use in the (outpatient) clinic, but it has several disadvantages: it needs patient*s understanding and co-operation, it is subjective and the reproducibility over time is limited. Moreover, an assessment of pain with the VAS for one patient may not imply the same intensity in another patient.
In patients unable to communicate their pain changes in heart rate and blood pressure are sometimes used to measure pain intensity. Heart rate variability is one of these methods. Heart rate variability is easy, reproducible and objective to measure. Most studies using heart rate variability as a measure of pain intensity have been performed in infants, mostly admitted to a NICU, and pain scores have been taken by trained nurses.
Therefore, to which extent heart rate variability is a measure of pain intensity should be further explored.

Study objective

The objective of this study is to determine whether heart rate variability measures correlate with pain intensity measured by a visual analogue scale in healthy volunteers in whom pain is induced by local heat application.

Study design

Healthy volunteers will be asked to participate in this study.
Volunteers will be asked to fill in the neuroticism subscale of the Eysenck Personality Questionnaire before the start of the procedure.
At baseline, pain intensity will be assessed by visual analogue scale. Heart rate will be measured continuously during the whole research period (about 30 minutes) using a Portapres. After obtaining five minutes of baseline heart rate recording, pain will be induced using local applied heat to the forearm. This stimulus will be continued during two minutes. After which volunteers will indicate on a VAS the intensity of the experienced pain. Thereafter, ten minutes of rest will be followed by application of the same pain stimulus and pain measurement. This procedure will be repeated twice.

Intervention

The Medoc Pathway System (Medoc ltd., Israel) equipment will be used to apply heat to the inner forearm. Before starting pain measurements the thermode will be placed on the forearm of the arm NOT containing the Portapres equipment necessary to measure the heart rate. This electrode is connected to the Pathway equipment which is programmed to induce heat during 2 minutes, starting at 45 degrees Celsius increasing every 10 seconds with 0.1 degree Celsius during

those two minutes. This will provide a stable pain intensity measured by the visual analogue scale.

Study burden and risks

-30 minutes time
-a moderate pain during apllication of the pain stimulus
-possible redness where the thermode has been placed

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

subjects able to have heart rate measures taken

subjects should have sinus rhythm

Exclusion criteria

subjects using medication other than oral anticonception

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2009
Enrollment:	70
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL26796.042.09