The effect of spinal anesthesia on pain perception and sedation in healthy volunteers

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(1) To assess the effect of deafferentation on pain processing in the brain by task-fMRI(2) To assess the effect of deafferentation on reaction time (sedation) by task-fMRI(3) To assess the effect of deafferentation on endogenous pain modulation

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

Summary

ID

NL-OMON38807

Source
ToetsingOnline

Brief title
the SAPP study

Condition

- Other condition
- Peripheral neuropathies

Synonym
chronic pain, neuropathic pain

Health condition

(chronische) neuropathische pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Deafferentation, Pain perception, sedation, Spinal anesthesia

Outcome measures

Primary outcome

fMRI measures (BOLD signal)

pain intensity (VAS)in response to a noxious thermal stimulus

reaction time after a cognitive test

Secondary outcome

n.v.t.

Study description

Background summary

Spinal anesthesia induces several alterations in normal brain processes. Firstly, loss of afferent information increases pain sensitivity. In our previous study on the effects of spinal anesthesia (P11.221) we showed that subjects felt more pain upon heat stimulation during spinal anesthesia. This increase in pain sensitivity was explained by alterations in the endogenous pain modulation system, which is an important regulator of pain perception. Secondly, clinical evidence suggests that the loss of afferent information from the spinal cord has significant effects on the maintenance of the arousal state. For example, spinal anesthesia coincides with the development of a decrease in the necessary dose of intravenous or inhalational anesthesia to reach a defined level of sedation. Furthermore, an increased level of sedation has been shown in healthy volunteers with spinal anesthesia.

Study objective

(1) To assess the effect of deafferentation on pain processing in the brain by task-fMRI

(2) To assess the effect of deafferentation on reaction time (sedation) by task-fMRI
(3) To assess the effect of deafferentation on endogenous pain modulation

Study design

The study will be performed using a single-blinded, placebo-controlled cross-over design. After arrival in the MRI suite, the subjects will be familiarized with the pain tests and cognitive test (reaction time and stop-signal test). Baseline pain sensitivity and reaction time will be measured and an intravenous access-line will be placed in the arm. Next, the first MRI scan session will be performed, which includes a baseline anatomical scan and baseline task-fMRI scans. The tasks that will be performed will be thermal pain tests and cognitive reaction time tests. Spinal anesthesia will be induced by intrathecal injection of the spinal anesthetic (bupivacaine) or a sham procedure will be performed. The block level and haemodynamic parameters (blood pressure and heart rate) will be determined at 5-minute intervals. 50 minutes post-injection the second MRI scan session will be started in which the tasks will be repeated. After the last scan, endogenous pain modulation will be tested by 2 methods, conditioned pain modulation and offset analgesia. These tests will be performed outside the MRI suite.

Intervention

spinal anesthesia

Study burden and risks

Small chance of post-spinal headache which will be treated where necessary

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

Healthy male volunteers, aged 18 to 45 years, right-handed.

Exclusion criteria

- Obesity (BMI > 30);
- Significant history of any cardiac or vascular disorder, asthma or other pulmonary disease, major gastrointestinal abnormalities, peptic ulceration, hepatic, neurological, psychiatric, hematological (including bleeding disorders), endocrine, renal, or major genitourinary disease;
- History of illness, condition or medication use that, in the opinion of the investigator, might interfere with optimal participation, confound the results of the study or pose additional risk in administering spinal anesthesia to the subject;
- History of chronic alcohol or illicit drug use;
- Metal medical devices like pacemakers, knee or hip prosthesis, ear implants, vessel clips, subcutaneous insulin pumps or carries metal particles (e.g. metal splinter in the eye) inside the body;
- Claustrophobia;
- Allergy to study medications;
- Not able to maintain a regular diurnal rhythm.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2013
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	12-06-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-02-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL43966.058.13