Het effect van de ruggenprik op pijn perceptie en sedatie in gezonde vrijwilligers

No registrations found.

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

Summary

ID

NL-OMON26547

Source
NTR

Brief title
SAPP

Health condition

pain processing
endogenous pain modulation
sedation
verwerken van pijnprikkels
endogene pijnstilling
sedatie

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: LUMC

Intervention

Outcome measures

Primary outcome

fMRI analysis, BOLD response.

Secondary outcome

experimental heat pain, performed with the Pathway (Medoc Ltd, Ramat Yishai, Israel), a device that is able to heat a probe to a predefined temperature.

Study description

Background summary

Spinal anesthesia induces several alterations in normal brain processes. Firstly, loss of afferent information increases pain sensitivity. Secondly, clinical evidence suggests that the loss of afferent information from the spinal cord has significant effects on the maintenance of the arousal state.

In this study the effects of deafferentation on pain perception and sedation will be further investigated by 1) performing task-related functional MRI and 2) performing behavioral pain tests to evaluate endogenous pain modulation.

Task-related fMRI: To determine the specific effects of deafferentation, two task-related fMRI scans will be performed to (1) detect the specific process of altered pain perception in the brain; and (2) measure reaction time as marker for sedation and identify alterations in brain regions involved in this process.

Endogenous pain modulation: A disbalance between pain facilitation and pain inhibition alters pain sensitivity and plays an important role in the chronification of pain. To evaluate the effect of deafferentation on the endogenous pain modulation system two experimental expressions of this system will be investigated known as the “Conditioned pain modulation” and “Offset analgesia” paradigm [10].

Aims:

(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 objective

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. The aim of the current study is to extend and specify the results seen in our previous study within specific pain processing brain areas with task-related fMRI data, and to evaluate experimental pain sensitivity and sedation after spinal anesthesia.

Study design

pre and post spinal scans (day 1 or 2) and control condition scans (day 1 or 2).

Intervention

We will perform fMRI scans and experimental pain tests prior to and after spinal anesthesia at the level of L4/5.

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Eligibility criteria

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
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-06-2013
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-07-2013
Application type:	First submission

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
NTR-new	NL3874
NTR-old	NTR4071
Other	: P13.070
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A