The effect of spinal anesthesia on resting-state fMRI.

No registrations found.

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

Summary

ID

NL-OMON22755

Source
NTR

Brief title
SpinMRI

Health condition

- spinal anesthesia
- deafferentiation

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

Resting-state fMRI.

Secondary outcome

1. Heat pain tests (heat probe on lower arm);

2. Sedation scoring (self test and observer test);

3. Block height.

Study description

Background summary

The influence of spinal injection on brain connectivity is not known. In this placebo-controlled randomized study healthy male right-handed volunteers will be injected wiht 3 mL bupivacaine 0.5% in the spinal space. Next resting-state fMRI will be obtained 1 and 2 hours after infection. The effect of deafferentiation on pain and sedation will be tested using heat pain tests and sedation self scoring and the Observer's Assessment of Alertness/Sedation Scale (OAA/S).

Study objective

1. The deafferentiation during spinal anesthesia changes the connectivity in resting-state networks in healthy volunteers;

2. The deafferentiation during spinal anesthesia changes pain perception and has sedetive effects.

Study design

1. Resting state fMRI: At baseline and at 1 and 2 hours after spinal infusion;

2. Heat pain tests: At baseline and at timepoint 15,30,45,90,105,150 minutes after spinal infusion;

3. Sedation scoring: At baseline and at timepoint 15,30,45,90,105,150 minutes after spinal infusion;

4. Block height: At baseline and at 10,20,30,45,90,105,150 minutes after spinal infusion.

Intervention

Spinal anesthesia at the level of L3-L4 with 3 mL bupivacaine 0.5% after local anesthesia with lidocaine 1%. Placebo will exist of local anesthesia with lidocaine after which a punction will take place to mimic the spinal punction.

The spinal anesthesia will last 4-5 hours. fMRi and arterial spin labeling will be performed 1 and 2 hours after anesthesia. Betweens these scans, heat pain tests will be performed on the forearm to evaluate the effect of spinal anesthesia on pain perception in areas not affected by the anesthesia.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy male, right handed volunteers between 18 and 45 years old.

Exclusion criteria

1. Obesity (BMI > 30);

2. Significant history of any cardiac or vascular disorder, asthma or other pulmonary disease, major gastrointestinal abnormalities, peptic ulceration, hepatic, neurological, psychiatric, haematological (including bleeding disorders), endocrine, renal, or major genitourinary disease;

3. 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;

4. History of chronic alcohol or illicit drug use;

5. 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;

6. Claustrophobia;

7. Allergy to study medications;

8. Not able to maintain a regular diurnal rhythm.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2012
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-06-2012

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	NL3330
NTR-old	NTR3491
Other	METC LUMC : P11-221
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A