The effect of spinal anesthesia on resting-state fMRI.

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22755

Bron
NTR

Verkorte titel
SpinMRI

Aandoening

- spinal anesthesia
- deafferentiation

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Resting-state fMRI.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2012
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-06-2012

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3330
NTR-old	NTR3491
Ander register	METC LUMC : P11-221
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A