Quantitative Sensory Testing and Conditioned Pain Modulation in patients after cervical percutaneous cordotomy

Published: 20-05-2015
Last updated: 16-04-2024

To perform sensory testing in patients who have undergone a cervical percutaneous cordotomy. The sensory testing include 'quantitative sensory testing' according to the *the German Research Network on Neuropathic Pain* protocol and a *...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42734

Source
ToetsingOnline

Brief title
QST and CPM after cordotomy

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer pain

Health condition

therapieresistente, oncologische pijn

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cervical, Cordotomy, CPM, QST

Outcome measures

Primary outcome

The quantitative values, obtained from the QST en CPM tests, which have been

performed bilaterally.

Secondary outcome

Not applicable

Study description

Background summary

Cervical percutaneous cordotomy (CPC) is an invasive treatment, which sometimes is applied in palliative pain care. During a CPC, the spinothalamic tract is unilaterally destructed (level C1-C2) with a series of radiofrequency-lesions. The needle for the radiofrequency lesion is positioned under fluoroscopy or CT guidance. After the procedure, the vital sensibility of the contralateral side of the body, caudal to dermatome C5, is interrupted.

The guideline *diagnostiek en behandeling van pijn bij patiënten met kanker* worked out by '' de Nederlandse Vereniging voor Anesthesiologie' provides these recommendations:
-Unilateral cordotomy can be applied in cases of unilateral pain, caudal to dermatome C5
-Bilateral cordotomy is not recommended
-Cordotomy can only be applied in patients with a maximum life expectancy of 1 to 2 years
-Cordotomy should only be performed in clinics with expertise in this area.

Quantitative sensory testing (QST) has been developed in Germany by the German Research Network on Neuropathic Pain, DFNS, to characterize the somatosensory

phenotype of patients with neuropathic pain. QST is a standardized measurement which assesses the integrity of the entire peripheral nerve (receptor to brain), by applying several mechanical en thermal stimuli to the skin. In 2006, an article was published, where the authors describe reference values, obtained by applying the QST measurement to 180 healthy volunteers.

The QST measurement can be performed bilaterally within one patient, in this case the patient provides his or her own control values, In the current literature there has been one article published where patients were subjected to quantitative clinical tests after a CPC. However, this article was published before the standardized QST measurement was developed. Applying the standardized QST measurement to patients who underwent a CPC can yield valuable information concerning the integrity of the several neurological modalities after spinothalamic tract destruction.
Furthermore, performing a conditioned pain modulation (CPM) test on patients after CPC has not been described in the literature. We propose to assess whether the CPM is altered after CPC. We hypothesize that the pain tolerance is increased after interruption of the vital sensibility, however we do not know the contribution of the vital sensibility to the mechanism of CPM. Therefore performing this study is of crucial importance for understanding this mechanism.

Study objective

To perform sensory testing in patients who have undergone a cervical percutaneous cordotomy. The sensory testing include 'quantitative sensory testing' according to the *the German Research Network on Neuropathic Pain* protocol and a *conditioned pain modulation* test, to determine the function of the inhibitory pain mechanism.

Study design

We propose a prospective cohort study. Patiënt will be subject to sensory testing (quantitative sensory testing and conditioned pain modulation), which will be conducted in an outpatient setting.
We expect to include the required number of patients within 18 months.

Study burden and risks

The burden for the patient is a onetime visit to the outpatient clinic of the Erasmus MC Hospital in Rotterdam. The sensory testing will take approximately two hours. The sensory testing is non-invasive and there is no risk for permanent (tissue) damage.

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

-Cervical percutaneous cordotomy, 2-4 weeks prior to the sensory testing
-The cervical percutaneous cordotomy must have been successfull: a loss of vital sensibility (determined by a positive pin-prick: a sharp pinch applied with a paper clip) caudal to dermatome C5, contralateral to the cordotomy side.
-Informed consent must have been obtained

Exclusion criteria

-Neurological disease/ nerve conduction disorder, which will influence the results of a bilateral QST measurement
-Inability to understand and speak in dutch

-When the sensory testing will be too much of a burden for the patient (in terms of psychological capacity, logistic problems, or a very limited prognosis). The attending Anesthesiologist/Pain Specialist (P. Zomers) will determine this.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2015
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-05-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52551.078.15