Video-Assisted Cordotomy Study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22264

Source
NTR

Brief title
VAC-study

Health condition

chronic pain in terminal cancer

Sponsors and support

Primary sponsor: UMC Groningen, Dept. of Anaesthesiology
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Primary outcome measure will be safety measured by (S)AE, side effects and complications documentation.

Secondary outcome

The secondary outcomes include feasibility of the video endoscope (identification of anatomical structures and technical equipment), feasibility regarding preoperative MRI

(identification of anatomical structures), effectiveness regarding pain relief (NRS and BPI), effectiveness regarding QoL (EORTC QLQ-C15-PAL, PGIC and HADS) and postoperative assessment of the thermolesion (MRI report).

Study description

Background summary

In patients with severe refractory pain due to cancer, or in case of too many side effects, a cordotomy may be needed to achieve pain control. This is a proved to be successful treatment, increases quality of life and has low costs. However, the procedure is currently performed by just a few specialists due to the high requirements with regard to technical skills and safety. By adding a video endoscope to the cordotomy, we aim to rehabilitate the cordotomy by showing that this new video endoscopic cordotomy technique is safe, provides effective pain control and has very few and manageable complications.

Study objective

Video endoscopic cordotomy technique is safe, provides effective pain control and has very few and manageable complications

Study design

Baseline: QST, MRI, Questionnaires (EORTC, BPI, HADS), Clinical evaluation (NRS, pain medication, etc)
Treatment: SAEs and procedure related details
Hospitalization: SAEs, Clinical evaluation (NRS, pain medication, etc)
Two weeks: SAEs, MRI, Questionnaires (EORTC, BPI, HADS PGIC), Clinical evaluation (NRS, pain medication, etc)
Six weeks: SAEs, MRI, Questionnaires (EORTC, BPI, HADS PGIC), Clinical evaluation (NRS, pain medication, etc)

Intervention

In this study a video endoscope will be added to the cordotomy in two consecutive parts.

Study part A: Just like with the regular cordotomy technique a cannula will be inserted in the spinal space under fluoroscopy and with the use of a contrast medium. Before the regular technique continues, the video endoscope will be inserted via the already brought in cannula to visualize anatomical structures in the spinal space. After identification of the different anatomical structures, the video endoscope will be removed. Then the regular technique continues, by placement of a RF probe with the use of X-ray in the spinal cord. After safety checks to confirm whether the RF probe is placed correctly in the spinal cord, a RF thermolesion (=treatment) will be made.

Study part B: Just like with the regular cordotomy technique a cannula will be inserted in the spinal space under fluoroscopy and with the use of a contrast medium. However, the cannula is replaced by a cannula with two entry channels. In the first channel the video endoscope will be inserted. After video endoscopic identification of the spinal cord, a RF probe is inserted via the second channel in the spinal space. Under video endoscopic visualization the RF probe will be placed in the spinal cord. After safety checks to confirm whether the RF probe is placed correctly in the spinal cord, a thermolesion (=treatment) will be made.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 18 years old ;
2. Unilateral (refractory) cancer related pain below dermatome C5;
3. Numeric Rating Scale (NRS) ≥ 4;
4. Pharmacological therapy offers no or insufficient relief (anymore) and/or has too many side effects;
5. Life expectancy maximum 1 – 2 years;
6. Understanding of the Dutch language .

Exclusion criteria

1. Cordotomy in medical history;
2. Bilateral pain of equal etiology;
3. Coagulation disorder or increased bleeding tendency;
4. Increased intracranial pressure;
5. Known allergy to iodine (because contrast medium administration (Lipiodol));

6. Unable to lie still on the operating table (~ 45-60 minutes);
7. Unable to communicate adequately during procedure;
8. Absolute contraindications MR imaging.
9. Enrolled in any other clinical study within the duration of the current study;
10. Incapable of giving consent.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL9106
Other	UMCG Research Register number : 202000923

Study results