Video-Assisted Cordotomy Study

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22264

Bron
NTR

Verkorte titel
VAC-study

Aandoening

chronic pain in terminal cancer

Ondersteuning

Primaire sponsor: UMC Groningen, Dept. of Anaesthesiology
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Universitair Medisch Centrum Groningen
T.F. Buisman

050 3611464

Wetenschappelijk

Universitair Medisch Centrum Groningen
T.F. Buisman

050 3611464

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 .

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL9106
Ander register	UMCG Research Register number : 202000923

Resultaten