Percutaneous splanchnic nerve neurolysis vs. endoscopic ultrasound-guided celiac ganglia neurolysis

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We hypothesize that endoscopic ultrasound-guided celiac ganglia neurolysis (EUS-CGN) is more effective in achieving adequate pain reduction in malignant upper-abdominal pain or back pain than percutaneous splanchnic nerve neurolysis (P-SNN)

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

Samenvatting

ID

NL-OMON27412

Bron
Nationaal Trial Register

Verkorte titel
PERSEUS study

Aandoening

Chronic intractable abdominal/back pain
inoperable abdominal malignancy

chronische onhoudbare buik-/rugpijn
inoperabele maligniteit in buik

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary parameter is the difference in short-term efficacy between P-SNN and EUS-CGN.
• Pain is measured using a 11-point numeric rating scale (0-10) for upper abdominal or back pain. Pain is assessed after seven days, the patient is asked about the pain score with regard to the previous 24 hours. This is compared to the patients baseline pain score in order to determine the reduction in pain (=efficacy).
• Baseline pain score is based on an assessment by the patient. The average pain score from the three consecutive days prior to the procedure will be used to determine the baseline pain score.

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with intra-abdominal malignancies, especially pancreatic carcinoma, are often inoperable at the time of diagnosis. For those patients, palliative therapy is the only option. Intra-abdominal malignancies are often associated with severe chronic pain. Celiac plexus neurolysis (CPN), either as a replacement or in addition to opioid usage, is an effective treatment option. Traditionally, percutaneous CPN (P-CPN) is performed by an anesthesiologist. The anesthesiologist uses a percutaneous approach to block the celiac plexus itself or the splanchnic nerves (percutaneous splanchnic nerve neurolysis; P-SNN), from which the celiac plexus nerves originate. Reaching the celiac plexus using endoscopic ultrasound (EUS) is a good, if not better, alternative. Recently, injection of a neurolytic agent with EUS directly in the celiac ganglia (EUS-CGN) proved superior to EUS-CPN. Direct comparison between P-SNN and EUS-guided neurolysis in malignant intra-abdominal pain has not been performed. Therefore, we set out to perform such a study. Since EUS-CGN proved superior to EUS-CPN, this technique will be used. We hypothesize that EUS-CGN is more effective in achieving adequate pain reduction in malignant upper-abdominal pain or back pain than percutaneous splanchnic nerve neurolysis (P-SNN).

Doel van het onderzoek

We hypothesize that endoscopic ultrasound-guided celiac ganglia neurolysis (EUS-CGN) is more effective in achieving adequate pain reduction in malignant upper-abdominal pain or back pain than percutaneous splanchnic nerve neurolysis (P-SNN)

Onderzoeksopzet

Baseline (before neurolysis):

1. Patient characteristics

2. Karnofsky performance scale

3. Analgetics usage

4. EQ5D score

During neurolysis:

1. Time procedure

2. Number and size ganglia (in case of EUS-CGN)

3. mL of alcohol/ phenol injected

1 week after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

5. Side-effects during first week

2 weeks after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

1 month after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

2 months after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

3 months after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

4 months after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

5 months after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

6 months after procedure:

1. Pain diary (11-point numeric rating scale for upper abdominal or back pain)

2. analgetics usage

3. EQ5D questionnaire

4. Complications neurolysis/ opioids

Onderzoeksproduct en/of interventie

Patients are randomized to undergo either endoscopic ultrasound-guided celiac ganglia neurolysis or percutaneous splanchnic nerve neurolysis.

Contactpersonen

Publiek

P.O. box 85500
University Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Wetenschappelijk

P.O. box 85500
University Medical Center Utrecht

Department of Gastroenterology & Hepatology
Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Diagnosis of an inoperable malignant tumor in the abdomen by histopathological or imaging findings.

o Inoperable malignancy is defined as local tumor infiltration into surrounding organs, distant metastases or a poor general health due to serious concomitant disease.

• Baseline pain score of ≥3 on a 11-point numeric rating scale (0-10) for upper abdominal or back pain. This is assessed on the three consecutive days prior to the procedure and the average score is used as a baseline pain score.

• ≥18years old.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Previous CPN

• Patients with a poor mental condition or mental retardation, unable to understand the nature and possible consequences of the study

• Coagulopathy (INR>1.5, platelets<50.000/mm3) which has not been corrected prior to the procedure

• Pregnancy

• Previous participation in this trial

• Severe allergy to contrast

• Systemic infection or infection at the location of the first lumbar vertebra.

• Karnofsky performance scale of <30%

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	17-06-2014
Aantal proefpersonen:	94
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-11-2014
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	NL4762
NTR-old	NTR4890
Ander register	Ethical committee Utrecht : 14-133

Resultaten