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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27412

Source
Nationaal Trial Register

Brief title
PERSEUS study

Health condition

Chronic intractable abdominal/back pain
inoperable abdominal malignancy

chronische onhoudbare buik-/rugpijn
inoperabele maligniteit in buik

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

• Pain reduction as a result of P-SNN compared to EUS-CGN, expressed as the percentage reduction in pain 7 days after the procedure. This will be compared to the average pain score of the three consecutive days prior to the procedure (=baseline pain score).

• Long-term efficacy, assessed using the pain score at twelve weeks after the procedure. If a patient dies before this time, the last filled out pain score will be used.

• Proportion of complete response (pain score ≤1, seven days after the neurolysis) between P-SNN and EUS-CGN.

• Opioid usage pre- and post-neurolysis, converted to daily oral morphine equivalents.

• Major complications related/not related to neurolysis procedure (either P-SNN or EUS-CGN); defined as complications leading to hospitalization, unintended prolongation of hospitalization, death or repeat (endoscopic) intervention with/without a possible or definite association with neurolysis procedure as determined by the treating physician.

• Minor complications related/not related to neurolysis procedure; defined as minor complications with/without a possible or definite association with neurolysis procedure as determined by the treating physician.

• Common opioid related side effects: nausea, pruritus, constipation, and drowsiness.

• Side–effects of neurolysis; defined as transient diarrhea, back pain, pneumothorax or orthostatic hypotension up to 3 days post-neurolysis.

• Technical success; successful injection of phenol at the correct location, as confirmed with fluoroscopy (in both groups). Judgment is made by the physician performing the procedure.

• Experience of patients, assessed after the procedure in patients who were awake during the procedure.

• EQ5D quality of life questionnaire prior to the procedure, a week, two weeks and four weeks after the procedure and then monthly up to 6 months.

• Costs of both approaches.

• Time required for both procedures.

• Pain diary first week, diary evaluating side-effects first week.

• Survival in both groups (after stratifying for disease and disease state).

Study description

Background summary

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).

Study objective

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)

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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%

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-06-2014
Enrollment:	94
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-11-2014
Application type:	First submission

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	NL4762

Register	ID
NTR-old	NTR4890
Other	Ethical committee Utrecht : 14-133

Study results