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

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To compare the efficacy of P-SNN to EUS-CGN with regard to decreasing chronic malignant pain in patients with inoperable intra-abdominal malignancies.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41507

Source
ToetsingOnline

Brief title
PERSEUS-study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
cancer, intra-abdominal malignancy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: celiac plexus, malignancy, neurolysis, pain

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, due to an inoperable intra-abdominal malignancy. The pain score used to determine the primary outcome will be assessed seven days after the procedure. 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.

• Difference in 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.(Levy 1996)

• 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 adverse events: nausea, pruritus, constipation, and drowsiness.

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

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

• Experience of the patient (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 12 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. A type of P-CPN is splanchnic nerve neurolysis (P-SNN), where the nerves are damaged more cranially than with a celiac plexus neurolysis. 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 P-SNN.

Study objective

To compare the efficacy of P-SNN to EUS-CGN with regard to decreasing chronic malignant pain in patients with inoperable intra-abdominal malignancies.

Study design

Single center, open label, randomized controlled trial.

Intervention

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

Study burden and risks

The burden for participation is limited. The procedure is performed as per standard protocol. Follow-up consists of calls of approximately 5-10 minutes after the first, second and fourth week and monthly thereafter. The maximum follow-up duration is six months. Both procedures are part of standard clinical

care. Therefore, there are no additional risks involved with study participation. Known risks associated with CPN are; lower extremity weakness, paresthesia, pneumothorax and hematuria. Side-effects include local pain, transient diarrhea and transient hypotension. Severe adverse events are expected to occur equally among the two groups. As it is currently not known whether EUS-CGN is indeed more effective in reducing malignant intra-abdominal pain than P-SNN , the benefit of study participation is uncertain. A possible advantage is that patients are closely monitored. Should the pain recur, appropriate action can be taken quickly. Should EUS-CGN proof more effective as hypothesized, a subset of patients will benefit from participation in this trial since P-CPN is performed much more frequently than EUS-CGN in our hospital in daily practice.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Diagnosis of an inoperable malignant tumor in the upper 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 >=4 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.
• >17 years 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 11th thoracic 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
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	17-06-2014
Enrollment:	94
Type:	Actual

Ethics review

Approved WMO Date:	28-04-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-04-2015
Application type:	Amendment
Review commission:	METC NedMec

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	NL45617.041.14