Percutaneous Radiofrequent Lesioning of the Splanchnic Nerves in Patients with Chronic Pancreatitis

Published: 17-11-2010
Last updated: 06-05-2024

To evaluate the feasibility and efficacy of percutaneous radiofrequent lesioning of splanchic nerves (PRFLSN) in patients with pain caused by chronic pancreatitis. The primary goal is to determine if a 50% reduction in pain can be achieved for at...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON35283

Source
ToetsingOnline

Brief title
Percutaneous RF Lesioning Splanchnic Nerves in Chronic Pancreatitis

Condition

- Gastrointestinal inflammatory conditions

Synonym
Chronic pancreatitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chronic pancreatitis, Pain, Paintreatment, Radiofrequent Lesioning

Outcome measures

Primary outcome

The percentage of reduction of pain after PRFLSN for a period of at least 6

months and preferably one year.

Secondary outcome

* Level of pain reduction after PRFLSN compared to optimal medical treatment

* Reduction in the number of painful days per month

* Reduction of medication use (NSAID*s and opioids) (MQS)

* Quality of life (QLC-30, PAN-28 (chronic pancreatitis specific

questionnaire), EQ-5D, BDI)

* Reduction in number of man-lost days per month

* Weight gain

Study description

Background summary

Pain control is the most pressing problem in patients with chronic pancreatitis. Many methods have been advocated to control this pain. Unfortunately, these methods fail to control the pain in 20-50% of patients. Management of patients with intractable pain is difficult, often resulting in narcotic addiction. Percutaneous alcoholic block of the celiac plexus is, because of the risks of paralysis resulting from a transverse myelopathy and catastrophic haemorrhage resulting from injury to major abdominal vasculature, restricted to patients with intractable, severe pain due to terminal pancreatic cancer. Splanchnic nerve lesioning is a useful alternative to celiac plexus block in the management of patients with chronic upper abdominal pain. The predictable relationship of the splanchnic nerves to other structures allows for accurate needle placement and hence a low risk of iatrogenic damage.

Radiofrequent lesioning uses a high frequency alternating current to heat tissues leading to thermal coagulation. It produces predictable and accurate lesions.

Study objective

To evaluate the feasibility and efficacy of percutaneous radiofrequent lesioning of splanchic nerves (PRFLSN) in patients with pain caused by chronic pancreatitis. The primary goal is to determine if a 50% reduction in pain can be achieved for at least 6 months. Secondary objectives are reduction of opioid use and improvement of quality of life.

Study design

Single blind, intervention study.

Intervention

One group receives PRFLSN after a positive trial block with bupivacaine, the other group receives no extra treatment besides optimal medical treatment.

Study burden and risks

Agenda
* At inclusion: NRS 4 days 3 times a day, QLC-30, PAN-28, MQS, PD/M, EuroQol-5D (EQ-5D), BDI
* The intervention: PRFLSN or no intervention
* 1 week after intervention NRS 4 days 3 times a day, GPE, QLC-30, PAN-28, MQS,
* 1 month after intervention NRS 4 days 3 times a day, GPE, QLC-30, PAN-28, MQS, EQ-5D, BDI
* 2 months after intervention NRS 4 days 3 times a day, GPE, QLC-30, PAN-28, MQS
* 3 months after intervention NRS 4 days 3 times a day, GPE, QLC-30, PAN-28, MQS, PD/M, EQ-5D, BDI

Risks of PRFLSN
RF lesioning has a definite advantage over phenol and alcohol neurolytic techniques because the RF lesioning is circumscribed and controlled. The proximal and distal spread of the lesion beyond the uninsulated tip of the probe is only 1 mm and the cross sectional diameter of the lesion is 5-6 mm. There is no possibility of nerve root damage or destructive damage of epidural and subarachnoid structures assuming that electrode placement can be verified by fluoroscopy and pretesting with electrical stimulation and impedance monitoring.
Numbness or motor paralysis occurs very rarely as a consequence of the lesioning. The tissues can be injured anywhere along the needle if there is a break in the insulation. Therefore, sensory and motor stimulation is always a

prerequisite for such lesioning.
Pneumothorax and diarrhoea can occur following splanchnic nerve blocks. In a study by Raj et al. 31 patients underwent PRFLSN after a trial block with a local anaesthetic. There were no complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with chronic pancreatitis presenting with significant abdominal pain of pancreatic origin. Pain will be considered significant if there is at least 1 episode of pain every month requiring analgesics during the preceding 3 months, or at least 1 episode of severe pain requiring hospitalization in the preceding 3 months.
*Pancreatic pain (NRS-score >5 out of 10), resistant to medical therapy (including opiods), with a duration of at least three months

Exclusion criteria

Patients with pseudocysts, bile duct obstruction, duodenal obstruction or pancreatic cancer.
Age younger than 18 years
A noncooperative patient
Coagulopathy
Previous splanchnic nerve denervation
Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2011
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	17-11-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	0911111
CCMO	NL29137.068.09