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Early Endoscopic Ultrasonography (EUS)-guided coeliac plexus neurolysis versus opioids for the treatment of pain in pancreatic carcinoma

Submission date 27/06/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/06/2007	**Overall study status** Completed	
Last Edited 21/09/2007	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr A.M.C.J. Voorburg

Contact details
Academic Medical Centre
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 8712
a.m.voorburg@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
We want to investigate which treatment modality is better, the fentanyl patches or the Endoscopic Ultrasonography (EUS)-guided Coeliac Plexus Neurolysis (CPN). This has never been investigated before. We think that the latter treatment might be less effective than one would expect according to earlier studies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, active controlled, crossover multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pancreatic carcinoma

Interventions
Patients will be randomised according to two treatment algorithms. The first conventional type treatment algorithms consists of increasing dosages of transdermal fentanyl patches. In this algorithm, EUS-guided CPN (rescue) will only be performed in case of failure of opioid treatment because of insufficient pain relief (VAS score greater than or equal to 4) or unmanageable side effects. The second treatment algorithm consists of early (repeated) EUS-guided CPN. In case of insufficient pain relief after the second CPN, opioid treatment with transdermal fentanyl patches may be started. Adequate response to therapy (either after EUS-guided CPN or opioids) is defined as a pain score less than or equal to 3 on a scale from 0 - 10 (VAS score) and the absence of unmanageable opioid-related side effects.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Transdermal fentanyl patches

Primary outcome measure
Quality of Adjusted Life Years (QALYs) will be the primary outcome parameter. This is a composite endpoint linking survival and quality of life, i.e. the number of quality adjusted life years. These are based on biweekly assessments of health status with the EuroQoL questionnaire (EQ-5D). The utility of each observed health score profile on the EQ-5D will be derived from previous research in which the time trade off based elicitation technique during interviews with adults from the general population has been applied.

Secondary outcome measures
1. Health-related quality of life (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire [EORTC-QLQ-C30])
2. Survival
3. Opioid requirement
4. Health status (EQ-5D)
5. Adverse effects
6. Costs

Overall study start date
01/08/2006

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Cytological or histological proven irresectable pancreatic carcinoma
2. Chronic pain unresponsive to non-opioid analgesic drugs and low dose fentanyl (Durogesic®) transdermal patches (Visual Analogue Scale [VAS] score greater than three while using fentanyl transdermal patches maximum 50 ug/h, one patch per three days)
3. Age above 18 years
4. Karnovsky score greater than 30%

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
120

Key exclusion criteria
1. Previous coeliac plexus blockade
2. Use of opioids
3. Refusal to sign informed consent

Date of first enrolment
01/08/2006

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Gastroenterology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl#http://www.amc.uva.nl/

ROR

https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration