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Preoperative biliary drainage for pancreato-biliary tumours causing obstructive jaundice: DRainage versus OPeration

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 18/01/2010	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR234

Study information

Scientific Title

Acronym
DROP-trial

Study objectives
Early surgical treatment (exploration followed by resection [pancreatoduodenectomy] or bypass) in patients with obstructive jaundice due to a pancreatic head tumour is equivalent in terms of severe complications of treatment compared with patients who underwent preoperative biliary drainage (four weeks) and subsequent surgery, while reducing hospital stay, the number of invasive diagnostic procedures (Endoscopic Retrograde Cholangiopancreatography [ERCP]) and results in lower overall costs.

Ethics approval required
Old ethics approval format

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

Study design
Randomised active controlled parallel group 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
Jaundice, bile duct tumour, pancreas tumour, Papilla of Vater tumour

Interventions
Preoperative biliary drainage:
Drainage procedure will be performed within three days after randomisation for a total of four weeks.

1. ERCP and preoperative biliary drainage will be performed by an experienced endoscopist, preferably by endoscopically insertion of a (plastic) stent
2. One stent is generally sufficient because only distal obstruction is included
3. If ERCP is not successful, patient can be referred to a centre for a second attempt for endoscopic drainage or a percutaneous drainage will be performed according to local experience
4. Biliary drainage is considered adequate if a decrease of greater than 50% of serum bilirubin level is found after two weeks of drainage; otherwise the stent should be changed
5. Exactly four weeks of preoperative biliary drainage patients will undergo surgery. In case of complications after ERCP or during the biliary drainage period (cholangitis, stent occlusion) a stent exchange will be performed.
6. Other complications, such as bleeding or severe pancreatitis, should be treated according to the general locally accepted treatment protocol and/or consensus about management and could consequently lead to a delay of surgery
7. Preoperative nutritional support (e.g. consultation with a dietician, nutri-drink) is recommended in patients with a weight loss of more than 15% during the last three months

Surgical treatment:
Surgery will be performed within one week after randomisation. Guidelines for exploration and treatment are described below:

1. Surgery should be planned keeping in mind that the maximum estimated bilirubin level (greater than 40 µmol/l and less than 250 µmol/l at randomization) must not exceed 300 µmol/l, 24 hours before surgery (e.g. high bilirubin at randomization requires earlier surgery)
2. Vitamin K (10 mg, oral, one day preoperatively) is given on indication and cefuroxim (1500 mg, intravenous single shot, ½ hour preoperatively) and sandostatin (or other analogues) (three times 100 µg, subcutaneous, 12 hours before surgery and continued for seven days after surgery) as prophylaxis
3. During exploration the standard procedure will be the standard pylorus preserving pancreatoduodenectomy as previously described (removal lymph nodes right side of portal vein). If indicated (suspicious ingrowth proximal duodenum/pylorus), a whipple procedure can be performed. In case of minimal vascular ingrowth a wedge resection of the portal/mesenteric vein can be performed
4. Reconstruction is performed by pancreaticojejunostomy, a hepaticojejunostomy and gastrojejunostomy
5. One silicone drain is placed near the pancreaticojejunostomy and/or one near the hepaticojejunostomy; T-drains will not be used
6. A feeding jejunostomy is not to be used as standard treatment
7. If resection is not performed due to metastases or local ingrowth biopsies have to be taken

Palliative treatment should be performed by a hepaticojejunostomy with gastroenterostomy plus a celiac plexus blockade. If a hepaticojejunostomy is not possible a wall stent should be placed during a postoperative ERCP session.

Please note that the anticipated end date of this trial has been extended to the 1st November 2007.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Percentage of patients with severe complications due to drainage or postoperative within 120 days after randomisation (90 days after surgery).

Secondary outcome measures
1. Hospital stay
2. Number of extra invasive diagnostic procedures
3. Costs
4. Quality of life
5. Analysis of CT criteria for resectability

Overall study start date
01/11/2003

Completion date
01/11/2006

Eligibility

Key inclusion criteria
1. Clinical diagnosis of obstructive jaundice due to a pancreatic head or periampullary tumour
2. A serum bilirubin level of greater than 40 µmol/l and less than 250 µmol/l at randomisation
3. A spiral Computed Tomography (CT) scan according to standard protocol without metastases or local tumour ingrowth in the portal or mesenteric vessels of greater than 180°
4. Referred for surgical treatment to one of the participating centres
5. Time between CT and randomisation less than or equal to four days
6. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
210

Key exclusion criteria
1. Aged greater than 85 years or severe co-morbidity (Karnofsky less than 50%) and other contra-indications for major surgery
2. Cholangitis/infection
3. Previous ERCP and stenting or percutaneous biliary drainage

4. Previous chemotherapy for this malignancy
5. Severe gastric outlet obstruction (stenosis duodenum due to tumour growth) defined as vomiting, nausea and/or oral intake less than 1 l/day

Date of first enrolment
01/11/2003

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (Netherlands)

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Sponsor type
University/education

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

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/03/2007		Yes	No
Results article	results	14/01/2010		Yes	No