

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

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<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/01/2010	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

### Study type(s)

Treatment

### 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  $\mu\text{mol/l}$  and less than 250  $\mu\text{mol/l}$  at randomization) must not exceed 300  $\mu\text{mol/l}$ , 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  $\mu\text{g}$ , 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(s)**

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

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**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  
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## Sponsor information

**Organisation**  
Academic Medical Centre (Netherlands)

**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

**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?
<a href="#">Results article</a>	results	14/01/2010		Yes	No
<a href="#">Protocol article</a>	protocol	12/03/2007		Yes	No