Preoperative biliary drainage with metal stent.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26508

Source
NTR

Health condition

periampullary cancer, jaundice, pancreas tumor

Sponsors and support

Primary sponsor: Academic Medical Center (AMC)
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The incidence of stent-related complications after preoperative biliary drainage with a metal stent. These results will be compared to those of the patients from the previous DROP trial (NTR NUMBER: NTR234) who underwent preoperative drainage with a plastic stent as well as patients without stenting.

Secondary outcome

1. Hospital stay;

2. Number of extra invasive diagnostic procedures;

3. Costs;

4. Quality of Life.

These results will be compared to those of the patients from the previous DROP trial (NTR NUMBER: NTR234) who underwent preoperative drainage with a plastic stent as well as patients without stenting.

Study description

Background summary

Surgery in patients with obstructive jaundice caused by a periampullary (pancreas, papilla, distal bile duct) tumor is associated with a higher risk of postoperative complications then non-jaundiced patients. Preoperative biliary drainage (PBD) was introduced in an attempt to improve the general condition and thus reduce postoperative morbidity and mortality though different studies failed to report all the positive effects of drainage. In respect to the ongoing controversy of PBD a multicentre randomized controlled trial: DROP trial, was conducted comparing PBD followed by surgery, with surgery alone. Significantly more severe complications were reported in the preoperative drained patients. Many of these complications were stent related. It was concluded that early surgery should be performed in patients with a resectable periampullary tumor. For patients who still are selected for preoperative drainage due to waiting time, neo-adjuvant treatment or preoperative staging recent literature suggests the use of metal stents instead of plastic stents to initiate drainage. Metal stents have longer patency and occlude less often. Today still up to 60% of patients operated for resectable pancreatic cancer have been drained preoperative with plastic stents. We hypothesize that the use of metal stents in preoperative biliary drainage will be associated with lesser complications then preoperative biliary drainage with plastic stents and by that reduce overall complications of surgery.

Study objective

Preoperative biliary drainage with metal stent in patients with resectable periampullary cancer results in less stent-related and drainage-related complications when compared to preoperative biliary drainage with plastic stents.

Study design

N/A

Intervention

ERCP with placement of metal stent instead of plastic stent in jaundiced patients with resectable periampullary cancer.

Contacts

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Eligibility criteria

Inclusion criteria

1. Clinical diagnosis of obstructive jaundice due to a pancreatic head or periampullary tumor;

2. A serum bilirubin level of > 40 µmol/l and < 250 µmol/l before inclusion;

3. A spiral CT scan according to standard protocol without metastases or local tumor ingrowth in the portal or mesenteric vessels of >180 degrees;

4. Scheduled for preoperative biliary drainage by principal physician;

5. Scheduled for surgical treatment in one of the participating centres.

Exclusion criteria

1. Age > 85 years or severe co-morbidity (Karnofsky <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 tumor growth) defined as vomiting, nausea and/or oral intake less than one l/day.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2011
Enrollment:	102
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-11-2011
Application type:	First submission

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
NTR-new	NL2994
NTR-old	NTR3142
Other	METC AMC : W11_82
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Preoperative biliary drainage for cancer of the head of the pancreas.
van der Gaag NA, Rauws EA, van Eijck CH, Bruno MJ, van der Harst E, Kubben FJ, Gerritsen JJ, Greve JW, Gerhards MF, de Hingh IH, Klinkenbijl JH, Nio CY, de Castro SM, Busch OR, van Gulik TM, Bossuyt PM, Gouma DJ. N Engl J Med. 2010 Jan 14;362(2):129-37.
Therapeutic delay and survival after surgery for cancer of the pancreatic head with or without preoperative biliary drainage.
Eshuis WJ, van der Gaag NA, Rauws EA, van Eijck CH, Bruno MJ, Kuipers EJ, Coene PP, Kubben FJ, Gerritsen JJ, Greve JW, Gerhards MF, de Hingh IH, Klinkenbijl JH, Nio CY, de Castro SM, Busch OR, van Gulik TM, Bossuyt PM, Gouma DJ. Ann Surg. 2010 Nov;252(5):840-9.
Preoperative biliary drainage in patients with obstructive jaundice: history and current status.
van der Gaag NA, Kloek JJ, de Castro SM, Busch OR, van Gulik TM, Gouma DJ.
J Gastrointest Surg. 2009 Apr;13(4):814-20.
Preoperative biliary drainage for periampullary tumors causing obstructive jaundice; DRainage vs. (direct) OPeration (DROP-trial).
van der Gaag NA, de Castro SM, Rauws EA, Bruno MJ, van Eijck CH, Kuipers EJ, Gerritsen JJ, Rutten JP, Greve JW, Hesselink EJ, Klinkenbijl JH, Rinkes IH, Boerma D, Bonsing BA, van Laarhoven CJ, Kubben FJ, van der Harst E, Sosef MN, Bosscha K, de Hingh IH, Th de Wit L, van Delden OM, Busch OR, van Gulik TM, Bossuyt PM, Gouma DJ. BMC Surg. 2007 Mar 12;7:3.
Delayed massive hemorrhage after pancreatic and biliary surgery: embolization or surgery?

de Castro SM, Kuhlmann KF, Busch OR, van Delden OM, Lameris JS, van Gulik TM, Obertop H, Gouma DJ. Ann Surg. 2005 Jan;241(1):85-91.
A meta-analysis on the efficacy of preoperative biliary drainage for tumors causing obstructive jaundice.
Sewnath ME, Karsten TM, Prins MH, Rauws EJ, Obertop H, Gouma DJ. Ann Surg. 2002 Jul;236(1):17-27.