

Preoperative biliary drainage with metal stent.

Gepubliceerd: 14-11-2011 Laatste bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26508

Bron

NTR

Aandoening

periampullary cancer, jaundice, pancreas tumor

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC)

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 than 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 than preoperative biliary drainage with plastic stents and by that reduce overall complications of surgery.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Academisch Medisch Centrum

Meibergdreef 9

G4-149
J.A.M.G. Tol
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5662860

Wetenschappelijk

Academisch Medisch Centrum

Meibergdreef 9

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J.A.M.G. Tol
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5662860

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Clinical diagnosis of obstructive jaundice due to a pancreatic head or periampullary tumor;
2. A serum bilirubin level of $> 40 \mu\text{mol/l}$ and $< 250 \mu\text{mol/l}$ 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2011
Aantal proefpersonen:	102
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	14-11-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2994
NTR-old	NTR3142
Ander register	METC AMC : W11_82
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

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, Klinkenbijn 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, Klinkenbijn 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, Klinkenbijn 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.