Colonic stenting as bridge to surgery versus emergency surgery for management of acute left-sided malignant colonic obstruction: a multicenter randomized trial.

Gepubliceerd: 20-10-2006 Laatst bijgewerkt: 18-08-2022

Which treatment strategy is the most effective for patients with acute left-sided malignant colonic obstruction: either colonic stenting followed by elective surgery or emergency surgery.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28044

Bron
NTR

Verkorte titel
Stent-in 2 study

Aandoening

acute left-sided malignant colonic obstruction

Ondersteuning

Primaire sponsor: P. Fockens, MD, PhD,
professor of Endoscopy
Academic Medical Center
Dept. of gastroenterology, C2
PO Box 22700
1100 DE Amsterdam

the Netherlands
tel: 0031 (0)20 5663534
fax: 0031 (0)20 6917033
e-mail: p.fockens@amc.nl
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Effectiveness of both strategies in terms of quality of life, morbidity and mortality.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective: To compare colonic stenting followed by surgery with emergency surgery for the management of acute left-sided malignant colonic obstruction in terms of health-related quality of life, morbidity and mortality.
Study design: Prospective randomized multicenter trial.
Study population: Patients with acute left-sided malignant colonic obstruction.
Intervention: Patients will be randomized to either emergency surgery (current standard treatment) or colonic stenting as bridge to elective surgery.
Outcome measurements: Effectiveness and costs of both strategies. Effectiveness will be evaluated in terms of quality of life, morbidity and mortality. Quality of life will be measured with standardized questionnaires (EORTC QLQ-C30, EORTC QLQ-CR38 and EuroQol). Morbidity is defined as every event leading to hospital admission or prolonging hospital stay. Mortality will be analyzed as total mortality as well as procedure-related mortality.
Power/data analysis: Including 120 patients on a 1:1 basis will have 80% power to detect an effect size of 0.5 on the EORTC QLQ-C30 global health scale, using a two group t-test with a 0.05 two-sided significance level. Differences in quality of life and morbidity will be analyzed using mixed-models repeated measures analysis of variance. Mortality will be compared using Kaplan-Meier curves and log-rank statistics.
Economic evaluation: The total costs of treatment will be evaluated by counting volumes and calculating unit prices.
Time schedule: Patient inclusion from January 2007 until the 31st of December 2009. Interim analysis will be done after inclusion of 60 patients. Final analysis and reporting April/October 2010.

Doel van het onderzoek

Which treatment strategy is the most effective for patients with acute left-sided malignant colonic obstruction: either colonic stenting followed by elective surgery or emergency surgery.

Onderzoeksproduct en/of interventie

Patients will be randomized to either emergency surgery (current standard treatment) or colonic stenting as bridge to elective surgery.

Contactpersonen

Publiek

Academic Medical Center (AMC),
Department of gastroenterology, C2,
P.O. Box 22760

Ilja Peute
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)6 30023579

Wetenschappelijk

Academic Medical Center (AMC),
Department of gastroenterology, C2,
P.O. Box 22760

Ilja Peute
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)6 30023579

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Symptoms of left-sided (colon descendens, sigmoid or rectum) malignant colonic obstruction existing less than one week defined as obstructive symptoms with dilation of the colon on either plain abdominal X-ray and typical abnormalities on a gastrografin enema study or CT-abdomen with contrast, compatible with a malignant colonic stricture;
2. Age > 18 years;
3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Peritonitis, perforation, fever, sepsis or other serious complications demanding urgent surgery;
2. ASA IV or V;
3. Obstruction due to non-colonic malignancies or from a benign origin;
4. Distal tumor margin less than 10 cm from the anal verge.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-10-2006

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	NL796
NTR-old	NTR809
Ander register	: N/A
ISRCTN	ISRCTN46462267

Resultaten

Samenvatting resultaten
N/A