

Evidence-based treatment of patients with acute large bowel obstruction caused by colon cancer of the left colon: Applying a clinical decision guideline

Gepubliceerd: 07-07-2014 Laatste bijgewerkt: 18-08-2022

Elderly patients of 70 years and older with acute malignant left-sided colonic obstruction will have a better treatment outcome with the 'bridge to surgery' method by means of a colonic stent or transverse colostomy.

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

Samenvatting

ID

NL-OMON26596

Bron

NTR

Verkorte titel

CONSTRUCT

Aandoening

Colon cancer, malignant large bowel obstruction, stent, elderly patients.

Dutch: Obstructief coloncarcinoom, stent, ouderen.

Ondersteuning

Primaire sponsor: Academic Medical Centre (AMC) Amsterdam

Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In-hospital and 30-day mortality rate in the elderly patients (> 70 years).

Toelichting onderzoek

Achtergrond van het onderzoek

This is a Dutch, multicenter, prospective validation study of a clinical decision guideline for the treatment of patients with acute, left-sided, colonic cancer obstruction. According to the guideline, patients are divided into three groups:

- 1) Patients younger than 70 years will have emergency resection. Exceptions can be made for those who have an indication for neo-adjuvant treatment, severe comorbidities and incurable metastatic disease; they should receive a decompressing intervention.
- 2) Potentially curable patients of 70 years and older will have bridge to surgery treatment by colonic stent placement or transverse loop colostomy, depending on the stricture characteristics and the intention to start anti-angiogenic therapy.
- 3) Patients with incurable extensive metastatic disease or patients who are unfit to undergo surgical resection will be treated palliatively by stent placement or a diverting colostomy.

The primary outcome is 30-day mortality in the group of elderly patients (≥ 70 years).

Doel van het onderzoek

Elderly patients of 70 years and older with acute malignant left-sided colonic obstruction will have a better treatment outcome with the 'bridge to surgery' method by means of a colonic stent or transverse colostomy.

Onderzoeksopzet

Primary and secondary outcomes will be measured during hospital admission and during regular oncologic follow-up visits at the outpatient clinic according to the Dutch guideline on colorectal carcinoma.

Onderzoeksproduct en/of interventie

1. Patients younger than 70 years will have surgical resection. Exceptions can be made for those who have (1) an indication for neo-adjuvant treatment, (2) severe comorbidities, and

(3) incurable metastatic disease; they should receive a decompressing intervention.

2. Patients aged 70 years and older without incurable metastatic disease will initially have non-resectional decompression followed by elective resection (bridge to surgery treatment):

A) Patients with a malignant stenosis < 40 mm are eligible for colonic stent placement, which will be performed by an experienced gastroenterologist.

B) If stent insertion failed, if stricture characteristics are unfavourable for stent placement, or if systemic anti-angiogenic therapy is intended, a minimally invasive transverse loop colostomy is constructed.

Patients eligible for elective resection will be operated at least 7 days after initial decompression and no later than 4 weeks after initial presentation.

3. Patients of all ages with incurable extensive metastatic disease or patients who are unfit to undergo surgical resection will be treated palliatively by stent placement or a diverting colostomy. Patients who are fit enough to have palliative chemotherapy are best treated with a colostomy in case anti-angiogenic therapy will be administered because of the risk of tumour perforation when having a stent in situ.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with symptomatic malignant obstruction of the left colon (including the splenic flexure, descending colon and sigmoid) caused by colonic cancer who require an urgent intervention to alleviate the obstruction.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Suspicion of peritonitis due to perforation (tumour or cecum blow out).
- Patients with benign disease at pathology.
- Patients with obstruction caused by extracolonic malignancy.
- Patients with malignant obstruction of the right colon, i.e. proximal to the splenic flexure.
- Patients with obstruction caused by rectal cancer, as defined within 10 cm of the anal verge for this protocol.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart

(Verwachte) startdatum: 01-01-2015
Aantal proefpersonen: 195
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 07-07-2014
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	NL4497
NTR-old	NTR4673

Ander register Medisch Ethische Toetsingscommissie AMC : W14_164#14.17.0205

Resultaten