Colonic stenting or surgery in left sided colonic obstruction for disseminated incurable colorectal cancer: a multicenter randomised trial.

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Patient with incurable disseminated left-sided colonic cancer are better palliated by colonic stenting than surgery measured by hospital free survival in "good health"(WHO-score 0 or 1) Colonic stenting is cost effective in patients with...

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

Samenvatting

ID

NL-OMON21491

Bron
NTR

Verkorte titel
Stent-in I study

Aandoening

incurable left-sided colonic cancer

Ondersteuning

Primaire sponsor: Prof. Gunning-Schepers, MD, Ph.D.
Chaiman Board of Directors
PO Box 22660
1100 DD Amsterdam
Overige ondersteuning: ZonMW grand

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Total hospital free survival in good health (corrected for days with a WHO performance status > 1);
2. Integral costs (product of volume consumed care and prices of means (personnel, overhead, material and investments).

Toelichting onderzoek

Achtergrond van het onderzoek

Survival in patients with incurable colonic cancer is poor and is estimated at 9 months. Morbidity associated with surgery might jeopardize successful palliation of imminent obstruction and bleeding. After hospital discharge the patient has to recover from surgery and might not reach the preoperative condition anymore due to postoperative morbidity or progressive disease. Patients who had successful colonic stenting recover very quickly from the endoscopic procedure. However, little is known how effective palliative stenting is in terms of long term relief of obstructing symptoms and early and late procedural morbidity and mortality.

The object of this study is to compare palliative treatment of (imminent) left sided obstruction in incurable colonic cancer either by surgery or colonic stenting.

Primary efficacy parameters are hospital free survival in good health (corrected for performance status) and integral costs. Based on a mean survival of 40 + 6 weeks and a difference in hospital free survival in good health of 3 weeks in favour of colonic stenting a total of 170 patients have to be included.

Doel van het onderzoek

Patient with incurable disseminated left-sided colonic cancer are better palliated by colonic stenting than surgery measured by hospital free survival in "good health"(WHO-score 0 or 1) Colonic stenting is cost effective in patients with incurable disseminated left-sided colonic cancer.

Onderzoeksproduct en/of interventie

Surgical palliation versus "wait and see" policy and colonic stenting if obstruction is imminent.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Left sided colonic cancer (from left flexure to > 10 cm of anus);

2. Diagnosis histological proven;

3. No signs of double tumor;

4. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Potentially curable disease;

2. ASA IV or V;

3. Ileus;

4. Karnofsky index of < 50%.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-12-2004
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-08-2005
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	NL94
NTR-old	NTR125
Ander register	: 1206
ISRCTN	ISRCTN01790428

Resultaten

Samenvatting resultaten
Endoscopy(begin 2008) Stent-in I study