

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

Submission date 20/12/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/07/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.stent-in.nl>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1206

Study information

Scientific Title

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

Acronym

Stent-in I study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Colonic cancer

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

1. Procedural related hospital stay and mortality and morbidity
2. Efficacy of palliation of (imminent) obstruction (complaints, secondary operation or stent placement)
3. Quality of life

Overall study start date

01/12/2004

Completion date

01/01/2008

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility**Key inclusion criteria**

1. Left sided colonic cancer (from left flexure to greater than 10 cm of anus)
2. Diagnosis histological proven
3. No signs of double tumour
4. Informed consent

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

180

Total final enrolment

21

Key exclusion criteria

1. Potentially curable disease
2. American Society of Anaesthesiologists (ASA) IV or V
3. Ileus
4. Karnofsky index of less than 50%

Date of first enrolment

01/12/2004

Date of final enrolment

01/01/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Afd. Maag-, Darm- en Leverziekten, C2-220

Amsterdam

Netherlands

1105 AZ

Sponsor information**Organisation**

Academic Medical Centre (AMC) (Netherlands)

Sponsor details

Department of Obstetrics and Gynaecology

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

<http://www.amc.uva.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	premature closure results	04/11/2006	15/07/2021	Yes	No