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

Recruitment status Stopped	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Stopped	[X] Results		
Condition category	Individual participant data		
Cancer	Record updated in last year		
	Overall study status Stopped Condition category		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

- 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)

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes