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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Stopped	
Last Edited 15/07/2021	**Condition category** Cancer	

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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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