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Colonic stenting as bridge to surgery versus emergency surgery for management of acute left-sided malignant colonic obstruction: a multicentre randomised trial

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 10/10/2014	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.stent-in.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Stent-in 2 study

Study objectives
Which treatment strategy is the most effective for patients with acute left-sided malignant colonic obstruction: either colonic stenting followed by elective surgery or emergency surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled parallel-group multicentre 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
Acute left-sided malignant colonic obstruction

Interventions
Patients will be randomised to either emergency surgery (current standard treatment) or colonic stenting as bridge to elective surgery.

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Effectiveness of both strategies in terms of quality of life, morbidity and mortality.

Secondary outcome measures
Costs of both strategies.

Overall study start date
01/01/2007

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Symptoms of left-sided malignant colonic obstruction existing less than one week defined as obstructive symptoms with dilation of the colon on plain abdominal X-ray and typical abnormalities on a gastrografin enema study compatible with a malignant colonic stricture
2. Aged more than 18 years
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
120

Key exclusion criteria
1. Peritonitis, perforation, fever, sepsis or other serious complications demanding urgent surgery
2. American Society of Anesthesiologists (ASA) IV or V
3. Obstruction due to non-colonic malignancies or from a benign origin
4. Distal tumor margin less than 10 cm from the anal verge

Date of first enrolment
01/01/2007

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1100 DE

Sponsor information

Organisation
Academic Medical Center (AMC) (The Netherlands)

Sponsor details
Department of Gastroenterology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/#http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (AMC) (The Netherlands)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
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?
Protocol article	protocol	03/07/2007		Yes	No
Results article	results	01/04/2011		Yes	No
Results article	results	01/12/2014		Yes	No