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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

Registration date
28/12/2006

Overall study status
Completed

Last Edited
10/10/2014

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Effectiveness of both strategies in terms of quality of life, morbidity and mortality.

Key secondary outcome(s))
Costs of both strategies.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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)

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

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	results	01/04/2011		Yes	No
Results article	results	01/12/2014		Yes	No
Protocol article	protocol	03/07/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes