Urgent versus elective colonoscopy in acute lower gastrointestinal bleeding: a randomized controlled trial

Published: 28-01-2013
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To examine differences in hospital length of stay (LOS) in patients with acute LGIB receiving either urgent colonoscopy or standard elective colonoscopy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal haemorrhages NEC
Study type	Interventional

Summary

ID

NL-OMON41384

Source
ToetsingOnline

Brief title
Urgent versus elective colonoscopy in acute hematochezia

Condition

- Gastrointestinal haemorrhages NEC

Synonym
acute gastro-intestinal bleeding, acute hematochezia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: geen geldstroom;is niet van toepassing

Intervention

Keyword: acute lower gastrointestinal bleeding, colonoscopy

Outcome measures

Primary outcome

Hospital length of stay (LOS) in days.

Secondary outcome

Blood transfusion requirements, yield of colonoscopy, rebleeding, subsequent diagnostic or therapeutic interventions related to bleeding, need for additional diagnostic and/or therapeutic interventions, mortality, morbidity related to hospital stay and hospital charges

Study description

Background summary

The incidence of acute lower gastro-intestinal bleeding (LGIB) is 21 adults per 100.000 person years and is increasing with the ageing of the population. So far, literature has been inconclusive on the matter of early colonoscopy (within 24 hours of presentation).

Study objective

To examine differences in hospital length of stay (LOS) in patients with acute LGIB receiving either urgent colonoscopy or standard elective colonoscopy.

Study design

Non-blinded randomized controlled trail

Intervention

Early colonoscopy versus standard colonoscopy

Study burden and risks

Patients are treated in accordance to the guideline Acute Hematochezia of the Dutch Society for Gastrointestinal and Liver Diseases (2010). No extra examinations are required.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All adults aged 18 years or older, presenting with acute hematochezia in the emergency department are included when:
- able to provide written informed consent
- the last bloody bowel movement is within 24 hours of presentation

- an upper gastro-intestinal bleeding source is not suspected or excluded by upper endoscopy;Criteria for suspicion of an upper source are:
- blood urea > 10% of creatinin value
- collapse
- hemodynamic instability (one of the following high risk features present):
* heart rate > 100 beats/min
* systolic blood pressure < 100 mmHg
* orthostatic changes in systolic blood pressure >20 mmHg or in heart rate >20 beats/min
* blood transfusion or drop in haemoglobin >1 mmol/l within a 6 hour period

Exclusion criteria

Patients are excluded when:
- age < 18 years
- unable to provide written informed consent
- known or suspected acute ischemic bowel, perforation or peritonitis
- hemodynamic instability refractory to resuscitation
- coagulopathy refractory to correction
- documented pregnancy
- serious comorbidities that would preclude to use of colonoscopy in standard clinical practice (i.e. severe COPD, severe cardiovasculair comorbidity)
- decreased level of consiousness

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2013

Enrollment:	132
Type:	Actual

Ethics review

Approved WMO Date:	28-01-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	18-07-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	03-02-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL42123.098.12