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Is early colonoscopy in patients with acute rectal blood loss better than standard colonoscopy?

Submission date
26/06/2017

Recruitment status
No longer recruiting

Registration date
26/07/2017

Overall study status
Completed

Last Edited
01/03/2021

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Rectal blood loss is a frequently encountered medical condition and often requires in-hospital treatment. To determine the cause of blood loss, an endoscopic (a procedure that uses a camera attached on a thing long tube to see in the inside of the body) examination of the large intestine is usually performed (this is called a colonoscopy). Presently, there is not enough scientific evidence for the benefits of early colonoscopy (this is a colonoscopy within 24 hours after admission to the hospital), compared to colonoscopy within 1-3 days for patients with rectal blood loss. Possible advantages are a shorter stay in the hospital, less blood loss, earlier diagnosis of the cause of the blood loss and (if possible) earlier treatment of the underlying cause. The aim of this study is to examine the possible benefits of early colonoscopy.

Who can participate?
Adults aged 18 and older who have had a bloody bowel movement within 24 hours who come to the hospital

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the standard colonoscopy done within 24-72 hours of presenting at the hospital. Those in the second group receive a colonoscopy within 24 hours of presenting at the hospital. The colonoscopies are performed the same in each group. Participants are hospitalised after the procedure to monitor for blood loss. They are discharged according to the hospital's protocols. Participants attend a follow up visit where they are assessed for readmissions to the hospital, complications, and the yield of colonoscopy

What are the possible benefits and risks of participating?
Participants may benefit from receiving a quicker colonoscopy. There are no risks with participating in this study. Colonoscopy has a slight risks for bleeding (<5%) and perforation (0.001%) in the large bowel.

Where is the study run from?
Haaglanden Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
September 2012 to April 2015

Who is funding the study?
Haaglanden Medical Centre (Netherlands)

Who is the main contact?
Ms Inge van Rongen

Contact information

Type(s)
Public

Contact name
Ms Inge van Rongen

Contact details
Haaglanden Medical Center
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12-101

Study information

Scientific Title
Early versus standard colonoscopy: A randomised controlled trial in patients with acute lower gastro-intestinal bleeding

Acronym
BLEED study

Study objectives
Early colonoscopy will decrease length of hospital stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
METC Zuid-West Holland (Medical Ethical Committee South West Holland), 25/02/2013, ref: 12-101

Study design
Single centre non-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files (in Dutch)

Health condition(s) or problem(s) studied
Gastroenterology

Interventions
Patients presenting at the emergency department with acute hematochezia are consecutively included in the trial when they had an indication for clinical colonoscopy, according to the Dutch Guideline 'Bleedings of the gastrointestinal tract'. Participants are randomised 1:1 in parallel groups to either early colonoscopy (within 24 hours) or standard colonoscopy (within 24-72 hours). In case of a suspected upper source of bleeding, patients underwent an upper endoscopy first. When an upper bleeding source was excluded, they are randomised. If an upper bleeding source was confirmed, patients did not meet the inclusion criteria and are not eligible for the trial. An online randomisation programme is used (ALEA, designed by the Clinical Trial Centre Maastricht, The Netherlands), based on minimisation and including the stratification factors age (18-60 years and >60 years) and gender.

For both groups, colon preparation was performed using a polyethylene glycol-based solution.

Group 1: Participants in this group receive the colonoscopy within 24 hours. They have their bowel preparation done as soon as possible after inclusion in the study. If they are unable to drink (e.g. due to nausea or swallowing disorders) a nasogastric tube was placed.

Group 1: Participants in this group receive the standard colonscopy within 24-72 hours. When necessary, a nasogastric tube is placed.

All colonoscopies are performed by either one of the gastroenterologists (seven in total) in the Haaglanden Medical Centre or one of the residents in training for gastroenterology (under

supervision of a gastroenterologist). According to hospital protocol, all colonoscopies were performed with sedation using a combination of midazolam 5 mg/ml i.v. (Dormicum® , Roche B. V., Woerden, The Netherlands) and fentanyl 0.05 mg/ml i.v. (Hameln Pharma Plus GmbH, Hameln, Germany), dose depending on age and comorbidity.

The in-hospital treatment and discharge criteria are similar in both groups and in accordance with the hospital protocol. Once a participant is stabilized (hemodynamically stable, no visible active bleeding anstable hemoglobin level), they could be discharged from hospital.

Participants are followed for one month. The follow up comprised a visit to one of the gastroenterologists at the outpatient department, according to hospital protocol. If a participant does not attend the follow up visit, due to various reasons, the patient chart was retrospectively addressed to obtain data on readmissions and mortality.

Intervention Type
Other

Primary outcome measure
Hospital length of stay (in days) is measured calculated using the date and time of admission to hospital and the date and time of hospital discharge.

Secondary outcome measures
1. The yield of colonoscopy, defined as diagnosing either a confirmed or presumptive source of bleeding and treatment if feasible is obtained from electronic patient charts (colonoscopy reports)
2. The number of packed red blood cells is obtained from the electronic patient charts
3. Information on readmissions and the reason for readmission (rectal blood loss) is obtained from the electronic patient chart
4. Information on complications are obtained from the electronic patient chart
5. 30 day mortality is obtained from the electronic patient chart

Overall study start date
14/09/2012

Completion date
14/04/2015

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Last bloody bowel movement within 24 hours of presentation
3. Ability to provide informed consent
4. No suspicion of or exclusion of an upper gastrointestinal bleeding source

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
132

Key exclusion criteria
1. Known or suspected acute ischemic bowel, perforation or peritonitis
2. Hemodynamic instability refractory to resuscitation
3. Coagulopathy refractory to correction
4. Documented pregnancy
5. Serious comorbidities that would preclude the use of colonoscopy in standard clinical practice (i.e. severe COPD, severe cardiovascular comorbidity)
6. Decreased level of consciousness.

Date of first enrolment
08/05/2013

Date of final enrolment
14/03/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Haaglanden Medical Centre
The Hague
Netherlands
2501 CK

Sponsor information

Organisation
Research Fund of the Haaglanden Medical Centre

Sponsor details
Lijnbaan 32
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2501 CK

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v2tx290

Funder(s)

Funder type
Research council

Funder Name
Research Fund of the Haaglanden Medical Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ms. I. van Rongen, i.vanrongen@haaglandenmc.nl or inge.van.rongen@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1	26/07/2017	26/07/2017	No	Yes
Results article	results	01/09/2019	29/01/2019	Yes	No