

The use of bowel relaxant Buscopan® to improve the detection of colonic polyps during colonoscopy

Submission date 03/11/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/11/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/03/2019	Condition category Digestive System	☐ 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

BUSCOPAN_PDR1

Study information

Scientific Title

The influence of hyoscine N-butylbromide on the colonoscopic polyp detection: A prospective, double blind, randomised, placebo-controlled trial

Study objectives

To investigate whether the administration of Buscopan® will improve the detection, removal and harvesting of colonic polyps during colonoscopy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Submission to the Medical Ethics Committee at Isala Klinieken, Zwolle, The Netherlands expected by the end of November 2010

Primary study design

Interventional

Study design

Prospective double blind randomised placebo controlled trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Colonoscopy; Colonic polyp; Colorectal carcinoma

Interventions

Intravenous administration of Buscopan or 0.9% Natriumchloride Solutution (placebo) during colonoscopy.

No further interventions

The duration of the action of Buscopan is only 20 minutes, and in this time colonoscopy will be finished. Data on polyp removal etc will be recorded during colonoscopy. There will be no further follow up, but participants will be informed about the histology of removed polyps in the outpatient department, as per usual practice.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hyoscine N-butylbromide (Buscopan®)

Primary outcome(s)

The number of colonoscopies during which at least one polyp has been found divided by the total number of colonoscopies

Key secondary outcome(s)

1. Polyp detection score

During each colonoscopy the number and shape of the polyps will be recorded.

Polyps < 5 mm will confer 3 points

Polyps 5-10 mm will confer 2 points

Polyps > 10 mm will confer 1 point

Scores will be made for flat / broad based polyps as well as rounded / pedunculated polyps.

2. Polyp removal ratio

The number of removed polyps divided by the number of detected polyps

3 Pathology retrieval ratio

The number of polyps send for pathological investigation divided by the number of removed polyps

4 Influence of age category

Categories are: 30 - 50 years, 51 - 70 years and > 70 years.

5 Influence of diverticulosis category

Categories are: 1: 0-2 diverticula, 2: 3-10 diverticula, 3: 11-20 diverticula en 4: > 20 diverticula.

6 Influence of the endoscopist

Completion date

15/01/2012

Eligibility

Key inclusion criteria

1. Patients aged 30 years or older
2. Able to understand and give informed consent
3. Routinely referred for colonoscopy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pregnancy
2. Myasthenia gravis
3. Exacerbation of inflammatory bowel disease
4. Suspicion of ongoing diverticulitis
5. Expectation of an estimated probability of complete colonoscopy of less than 50%, e.g. by the presence of a stenosis

Date of first enrolment

15/01/2010

Date of final enrolment

15/01/2012

Locations

Countries of recruitment

Netherlands

Study participating centre

Department of Gastroenterology and Hepatology

Deventer

Netherlands

7416 SE

Sponsor information

Organisation

Deventer Hospital (Netherlands)

ROR

<https://ror.org/05w8df681>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Deventer Hospital (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	01/04/2012		Yes	No