

Is blinding the endoscopists to bowel preparations in randomised controlled trials a reality?

Submission date 23/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/10/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/08/2011	Condition category Surgery	☐ 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

Study information

Scientific Title

Acronym
PEG, NaP

Study objectives

The primary aim of this study was to explore whether endoscopists can be effectively blinded to the type of bowel preparation in the trials that compare the cleaning efficacy of oral sodium phosphate and polyethylene glycol

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Screening

Health condition(s) or problem(s) studied

Colonoscopy for screening, surveillance, or diagnosis of colorectal cancer

Interventions

Blinding the colonoscopists to the type of bowel preparation given prior to colonoscopy - oral sodium phosphate versus polyethylene glycol

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oral sodium phosphate and polyethylene glycol

Primary outcome(s)

The primary outcome of this study is to determine the proportion of correct estimation of the bowel preparation by all endoscopists combined

Key secondary outcome(s)

Secondary outcomes are the proportion of correct estimations by individual endoscopists. We are also interested in the distinguishing features that endoscopists reported as reasons for their judgments. Other secondary aims are the comparison of tolerability, safety, and overall quality of colon cleansing for the two bowel preparations.

Completion date

25/08/2004

Eligibility

Key inclusion criteria

All outpatient adults (18-65 years old) undergoing colonoscopy for screening, surveillance, or diagnosis of colorectal cancer at the Western NY Veterans Affairs Medical Center in Buffalo between May 2003 and August 2004 who had a basic metabolic profile blood test within one year prior to enrollment were eligible for this study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Key exclusion criteria

Patients were not eligible for the study if any of the following was present:

1. Evidence of renal insufficiency (creatinine >2.0 mg/dl)
2. Evidence of electrolyte abnormalities
3. Cardiovascular disease, including uncontrolled congestive heart failure (American Heart Association Functional Class III or IV), unstable angina, or myocardial infarction, percutaneous transluminal coronary angioplasty, cardiac surgery within the past 3 months
4. Inflammatory bowel disease
5. Colon disease, including chronic constipation (<2 bowel movements per week for >one year, ileus and/or acute obstruction, hypomotility syndrome, megacolon, idiopathic pseudo-obstruction, or previous colonic surgery
6. Pregnant or breastfeeding female

A meta-analysis that included randomised controlled trials comparing the two bowel preparations showed that clinical adverse effects were comparable in frequency when patients are carefully selected

Date of first enrolment

31/07/2003

Date of final enrolment

25/08/2004

Locations**Countries of recruitment**

Italy

United States of America

Study participating centre

Division of Clinical Research Development and Information Translation (INFORMA)

Rome

Italy

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Sponsor information

Organisation

State University of New York at Buffalo (USA)

ROR

<https://ror.org/01y64my43>

Funder(s)

Funder type

University/education

Funder Name

The office of graduate medical education at the State University of New York, Buffalo (USA)

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	01/01/2006		Yes	No