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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/10/2005	**Overall study status** Completed	
Last Edited 16/08/2011	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
31/07/2003

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
114 patients

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)

Sponsor details
The Office of Graduate Medical Education
117 Cary hall
3435 Main street
Buffalo
United States of America
14214

Sponsor type
University/education

Website

http://www.smbs.buffalo.edu/gme/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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