

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

<b>Submission date</b> 23/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/08/2011	<b>Condition category</b> Surgery	<input type="checkbox"/> 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

**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?
<a href="#">Results article</a>	results	01/01/2006		Yes	No