# Self-collection of stool: an alternative to digital rectal examination for faecal occult blood testing in the emergency department (ED)

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
23/11/2005		☐ Protocol		
Registration date 25/11/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 16/01/2020	Condition category	[] Individual participant data		
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# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Paris Lovett

#### Contact details

545 West 111th Street New York United States of America 10025

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

#### Scientific Title

Self-collection of stool: an alternative to digital rectal examination for faecal occult blood testing in the emergency department (ED)

#### **Study objectives**

Self-Collection of Stool (SCS) causes equal degrees of pain/discomfort and produces equally adequate specimens for occult blood testing when compared with the traditional technique employed in the Emergency Department - Digital Rectal Examination (DRE)

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Institutional Review Board of Beth Israel Medical Center, New York, NY, with written consent required

### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

#### Study type(s)

**Not Specified** 

## Participant information sheet

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

Stool Collection for Occult Blood Testing

#### Interventions

Stool Collection using either traditional DRE technique or new technique under study (SCS).

## Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Pain/Discomfort, measured on a 100 mm Visual Analog Scale (VAS)

### Secondary outcome measures

Adequacy of Specimen for Guaiac Testing

## Overall study start date

02/01/2004

## Completion date

30/05/2004

# **Eligibility**

#### Key inclusion criteria

All patients 18 years and older for whom the treating Emergency Physician (EP) had made a decision to collect stool were interviewed for enrollment.

## Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

### Target number of participants

28

## Key exclusion criteria

Subjects were excluded from enrollment if there was some indication that DRE instead of SCS would provide additional clinical information which might determine diagnosis or management. Such exclusions comprised patients with presenting complaints of anal or rectal pain, anal or rectal masses or swelling, possible spinal injury, prostatic disease, or urinary retention. Patients were also excluded if they were unable to give written consent in English, if they were judged incapable of performing SCS, or if stool had already been obtained.

#### Date of first enrolment

02/01/2004

#### Date of final enrolment

30/05/2004

# Locations

#### Countries of recruitment

United States of America

## Study participating centre

#### 545 West 111th Street

New York United States of America 10025

# Sponsor information

#### Organisation

New York-Presbyterian - University Hospital of Columbia and Cornell and Beth Israel Medical Center (USA)

#### Sponsor details

545 West 111th Street New York United States of America 10025

#### Sponsor type

Hospital/treatment centre

#### **ROR**

https://ror.org/03gzbrs57

# Funder(s)

# Funder type

Hospital/treatment centre

#### **Funder Name**

Beth Israel Medical Centre (Israel)

# **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	01/09/2005	16/01/2020	Yes	No