

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

Submission date 23/11/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/01/2020	Condition category Other	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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

Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Adequacy of Specimen for Guaiac Testing

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/03gzbrs57>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Beth Israel Medical Centre (Israel)

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