ISRCTN93236187 https://doi.org/10.1186/ISRCTN93236187

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

Registration date
25/11/2005

Overall study status
Completed

Last Edited
16/01/2020

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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United States of America
10025

Additional identifiers

Protocol serial number
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

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