

Evaluation of guidelines for open access flexible sigmoidoscopy

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/10/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Greg Rubin

Contact details
School of Science
University of Sunderland
Benedict Building
St Georges Way
Sunderland
United Kingdom
SR2 7BW
+44 (0)191 515 3831

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PSI B-10

Study information

Scientific Title

Study objectives

To evaluate the effect of guidelines on utilisation of an open access flexible sigmoidoscopy (OAFS) service and the subsequent clinical management of patients referred to it. To compare the management of patients referred to outpatient clinics or to OAFS in terms of process measures, clinical outcome and resource utilisation. To identify changes in referral case mix following introduction of guidelines for an OAFS.

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

1. Open access flexible sigmoidoscopy (OAFS) guidelines.
2. No guidelines.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Referrals/1000 population
2. Endoscopy findings
3. Final diagnoses
4. Time to diagnosis
5. Resource costs in primary and secondary care
6. Patient resource costs.

The introduction of the guideline had no significant effect on the selection of patients for investigation, but did influence patient management, both at the time of endoscopy and thereafter, the sum effect of which was reduced use of secondary care resources. GPs are selective in their use of an OAFS service for patients with rectal bleeding. The introduction of OAFS is cost effective and results in changes in case mix in referrals to specialist clinics. Non-malignant neoplasms were found more often in OAFS referrals, confirming the value of this service in evaluating low risk rectal bleeding.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/1997

Completion date

30/06/1999

Eligibility**Key inclusion criteria**

1. Patients referred for open access flexible sigmoidoscopy and their referring practices.
2. Patients with symptomatic rectal bleeding referred for outpatient assessment prior to and during the study period.
3. < 18 years old

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/03/1997

Date of final enrolment

30/06/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**School of Science**

Sunderland

United Kingdom

SR2 7BW

Sponsor information

Organisation

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Primary and Secondary Care Interface National Research and Development Programme (UK)

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	01/01/2000		Yes	No