

# Evaluation of guidelines for open access flexible sigmoidoscopy

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/10/2012	<b>Condition category</b> Cancer	<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**  
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?
<a href="#">Results article</a>	results	01/01/2000		Yes	No