

# The role of faecal occult blood testing in identifying subjects with iron deficiency anaemia who have underlying gastro-intestinal cancer

<b>Submission date</b> 17/06/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/05/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-whether-testing-poo-blood-can-show-who-might-be-at-risk-cancer-stomach-bowel>

## Contact information

### Type(s)

Scientific

### Contact name

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### ORCID ID

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### Contact details

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Poole  
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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## **Secondary identifying numbers**

N/A

# **Study information**

## **Scientific Title**

The role of faecal occult blood testing in risk stratification for GI malignancy in subjects with iron deficiency anaemia

## **Acronym**

IDIOM (3)

## **Study objectives**

Screening patients with iron deficiency anaemia by means of faecal occult blood testing can identify sub-groups at high risk of underlying gastro-intestinal malignancy, over and above the stratification provided by established clinical criteria.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Not provided at time of registration

## **Study design**

Single-centre cohort observation

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Screening

## **Participant information sheet**

See additional files

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

Iron deficiency anaemia caused by gastrointestinal malignancy

## **Interventions**

All patients in the study will have a qualitative immunochemical stool test for occult blood prior to gastro-intestinal investigation of the cause of their anaemia.

All patients will be followed up until they have completed investigation of their iron deficiency anaemia, as clinically indicated. The study will assess whether faecal occult blood (FOB) testing at presentation can predict the likelihood of underlying gastrointestinal pathology in subjects with iron deficiency anaemia (IDA) and, in particular, cancer.

**Intervention Type**

Other

**Primary outcome measure**

The predictive value of immunochemical faecal blood testing for gastrointestinal malignancy

**Secondary outcome measures**

The predictive value of immunochemical faecal blood testing for:

1. Colorectal cancer
2. Any bleeding lesion

**Overall study start date**

01/09/2015

**Completion date**

30/06/2018

**Eligibility****Key inclusion criteria**

Confirmed iron deficiency anaemia

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

357

**Total final enrolment**

62

**Key exclusion criteria**

1. Aged under 18
2. Lack of capacity to provide informed consent and to undertake stool collection
3. Decision not to undergo investigation to establish the cause of iron deficiency

**Date of first enrolment**

01/07/2016

**Date of final enrolment**

30/06/2018

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Poole Hospital NHS Foundation Trust**

Longfleet Road

Poole

United Kingdom

BH15 2JB

## **Sponsor information**

**Organisation**

Poole Hospital NHS Foundation Trust

**Sponsor details**

Longfleet Road

Poole

England

United Kingdom

BH15 2JB

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03kdm3q80>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

## Results and Publications

### Publication and dissemination plan

Publication in a peer-reviewed journal

### Intention to publish date

31/12/2020

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		21/06/2016	20/09/2016	No	Yes
<a href="#">Results article</a>	results	21/05/2020	13/07/2020	Yes	No
<a href="#">Plain English results</a>			16/05/2023	No	Yes