

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

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

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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?
Participant information sheet	results	21/06/2016	20/09/2016	No	Yes
Results article		21/05/2020	13/07/2020	Yes	No
Plain English results			16/05/2023	No	Yes