ISRCTN18342140 https://doi.org/10.1186/ISRCTN18342140

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

Registration date
15/09/2016

Overall study status
Completed

Last Edited
16/05/2023

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Dr Jonathon Snook

ORCID ID
https://orcid.org/0000-0002-3172-2722

Contact details
Poole Hospital NHS Foundation Trust
Poole
United Kingdom
BH11 9NG

Additional identifiers

Protocol serial number
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

Study type(s)
Screening

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(s)
The predictive value of immunochemical faecal blood testing for gastrointestinal malignancy

Key secondary outcome(s))
The predictive value of immunochemical faecal blood testing for:
1. Colorectal cancer
2. Any bleeding lesion

Completion date
30/06/2018

Eligibility

Key inclusion criteria
Confirmed iron deficiency anaemia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust

ROR
https://ror.org/03kdm3q80

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Poole Hospital Gastroenterology Research Fund

Results and Publications

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?
Results article	results	21/05/2020	13/07/2020	Yes	No
Participant information sheet	Participant information sheet	21/06/2016	20/09/2016	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Plain English results			16/05/2023	No	Yes