

FIT— Can a Dipstick Test Rule Out Bowel Cancer?

Submission date 11/09/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/12/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/01/2023	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-at-a-new-test-called-fit-to-look-for-signs-of-bowel-cancer-nice-fit>

Contact information

Type(s)

Scientific

Contact name

Mr Nigel D'Souza

ORCID ID

<http://orcid.org/0000-0002-9614-6113>

Contact details

Academic Colorectal Unit
Croydon University Hospital
Croydon
United Kingdom
CR7 7YE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

35915

Study information

Scientific Title

NICE Guidelines and the place of the Faecal Immunochemical Test as a triage tool for predicting Bowel Cancer

Acronym

NICE FIT

Study objectives

Hypotheses:

1. To investigate whether FIT can be used as an effective triaging tool in primary care to decide whether patients referred under the two week rule should undergo endoscopic investigation.
2. To determine appropriate cut-off levels for subgroups based on age, sex, ethnicity and socioeconomic deprivation

Ethics approval required

Old ethics approval format

Ethics approval(s)

London South East Research Ethics Committee REC,18/05/2017, ref: 16/LO/2174

Study design

Non-randomised; Interventional; Design type: Diagnosis, Device

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

All participants recruited in the study are asked to complete a stool sample, and return it to the laboratory for FIT analysis. The faecal haemoglobin level are compared to the findings from the colonoscopy.

Intervention Type

Other

Primary outcome measure

1. Identify a suitable cut-off for the test
2. Calculate the sensitivity of the test using the chosen cut-off for colorectal polyps

Secondary outcome measures

1. Calculate the specificity, negative- and positive-predictive values for the chosen cutoff
2. Explore the effects of other prognostic factors on the sensitivity and the suitability of the cut-off value:
 - 2.1. Cancer site
 - 2.2. Site and size of adenomas
3. Assessing the levels of FHB in benign non-neoplastic pathology

The above data will be collected from reviewing patient notes and correlated with the faecal haemoglobin detected by the lab.

Overall study start date

06/01/2017

Completion date

01/06/2019

Eligibility**Key inclusion criteria**

1. All patients referred under the 2WW urgent referral system and triaged for a colonoscopy examination
2. 18 years of age or older
3. Willing to provide informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 6000; UK Sample Size: 6000

Total final enrolment

9822

Key exclusion criteria

1. Unable to undergo colonoscopy
2. Unable to take adequate stool sample (including those taken during bowel preparation)
3. Unable to give an informed consent due to lack of capacity
4. Unable to give informed consent because of language barrier, when a relative over 18 is unable to translate, a staff member who speaks the same language cannot be found, or online translation service are unsuccessful

Date of first enrolment

01/04/2017

Date of final enrolment

31/03/2019

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Mayday University Hospital**

Croydon Health Services NHS Trust
London Road
Thorton Heath
United Kingdom
CR7 7YE

Study participating centre**St Marys Hospital**

Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre**Chelsea & Westminster Hospital**

Chelsea & Westminster Hospital NHS Foundation Trust
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre

The Hillingdon Hospitals NHS Foundation Trust

Pield Heath Road
Middlesex
Uxbridge
United Kingdom
UB8 3NN

Study participating centre

Northwick Park Hospital

London North West Healthcare NHS Trust
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre

Kingston Hospital NHS Foundation Trust

Galsworthy Road
Kingston Upon Thames
United Kingdom
KT2 7QB

Study participating centre

St George's Hospital

St George's University Hospital NHS Foundation Trust
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre

Royal Surrey County Hospital NHS Foundation Trust

Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre

St Helier Hospital

Epsom and St Helier University Hospitals NHS Trust
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre

Southampton General Hospital

Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre

St Peter's Hospital

Ashford and St Peter's Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre

King's College Hospital

Denmark Hill
King's College Hospital NHS Foundation Trust
London
United Kingdom
SE5 9RS

Study participating centre

University Hospital Lewisham

Lewisham and Greenwich NHS Trust
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre

Worthing Hospital

Western Sussex Hospitals NHS Foundation Trust
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre**Kent & Canterbury Hospital**

East Kent Hospitals
University NHS Foundation Trust
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre**East Surrey Hospital**

Surrey and Sussex Healthcare NHS Trust
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre**Salisbury District Hospital**

Salisbury NHS Foundation Trust
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre**Hampshire Hospitals NHS Foundation Trust**

Aldermaston Road
Hampshire
Basingstoke
United Kingdom
RG24 9NA

Study participating centre

Dorset Healthcare University NHS Foundation Trust
Sentinel House
4-6 Nuffield Road
Nuffield Industrial Estate Poole Dorset
Poole
United Kingdom
BH17 0RB

Sponsor information

Organisation

Croydon Health Services NHS Trust

Sponsor details

Croydon University Hospital
London Road
Thornton Heath
England
United Kingdom
CR7 7YE

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00sh7p618>

Funder(s)

Funder type

Government

Funder Name

NHS England

Funder Name

Alpha Laboratories Limited

Results and Publications

Publication and dissemination plan

The data will be published upon study completion. Submission for publication in a high impact journal should hopefully occur before December 2018. It will be presented at national and international conferences.

Data will be shared with NHS England, who will pool it with data from other FIT trials.

Intention to publish date

01/06/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (at Croydon University Hospital, that will be shared with NHS England only).

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4.1	25/05/2017	19/12/2017	No	Yes
Results article	results	21/10/2020	23/10/2020	Yes	No
Other publications	Patient survey substudy	22/03/2022	18/01/2023	Yes	No
HRA research summary			28/06/2023	No	No