

# qFIT

IRAS: 213710

## A new test for ruling out colorectal cancer - The qFIT Pilot

### Objectives

Our primary objective is to test and validate the accuracy and process of the qFIT test as a direct access test for patients with suspected colorectal cancer.

Our secondary objectives are:

- To understand qFIT test uptake (i.e. % of eligible patients who were given the qFIT test and decided to participate in the study)
- To determine lower-,and upper cut-off haemoglobin concentrations in stool in order to define 'rule-out' and 'rule-in' haemoglobin concentrations in stool for colorectal cancer.
- To understand whether age, gender, ethnicity or deprivation affect haemoglobin levels in stool and hence influence the outcome of the qFIT test
- To evaluate the effect of abnormal FBC (including IDA) on qFIT results
- To prospectively test an algorithm processing FBC data in conjunction with qFIT
- To evaluate patient experience in the qFIT pilot.

### Design

Observational Pilot Study

**Dr Michael R Machesney (CI)**

University College London (Sponsor)

**£239.76**

*Total maximum payment based on combined costs*

### Patient

#### Benefits

The qFIT pilot study will benefit future patients for who suspected colorectal cancer can be ruled out without needing to go through a colonoscopy.

#### Involvement

The patient will be asked to take a single sample at their next bowel movement and send the test to a dedicated lab via post.\*

#### Eligibility

##### Inclusion

- 16years and above
- Patients who had been referred from a participating GP practices in London for a 2ww appointment to examine the lower gastrointestinal tract
- Patients who had been referred to participating NHS Trusts in London for a 2ww appointment to examine the lower gastrointestinal tract

##### Exclusion

- Patients who receive a non-urgent lower gastrointestinal tract examination referral
- who are under 16 years of age
- unable to understand instructions (including non-English speakers)
- Those referred for investigation of a positive test result from the Bowel Screening Programme in England.

### Finance

Support Costs      £239.76

### Practice

#### Benefits

We hope that by reducing the number of unnecessary colonoscopies, hospitals will be able to offer appointments sooner for those patients who need the test. This pilot study will help to guide the NHS.

#### Activities

##### GP

Provide qFIT test kit to patients in-consultation when making a 2ww referral for patient with lower GI symptoms

##### Practice Manager

n/a

##### Practice Nurse

n/a

##### Administrator

Share qFIT hand-out booklet data with study team on an onthly basis and monitors qFIT kit stock and notifies study team when top up is required

##### Receptionist

n/a

### Recruitment Numbers

Screen	Invite	Recruit
n/a	80	44

### Time to Complete

6 months

\*Completing the qFIT test does not change the patient's pathway. No intervention will be made to treatment plan based on the outcome of the qFIT test, therefore the patient will not be notified about qFIT test outcome