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Assessment of the impact on chemotherapy decision-making and cost effectiveness of the integration of the digital biomarker test OncoProg into early stage colon cancer treatment pathways

Submission date
28/08/2024

Recruitment status
Recruiting

Registration date
11/09/2024

Overall study status
Ongoing

Last Edited
10/09/2024

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Every year, about 42,000 people in the UK are diagnosed with bowel cancer, and around half of these cases are classified as early-stage (stage II and IIA). Deciding whether these early-stage patients should receive chemotherapy is difficult because only a small number of them actually benefit from it. Currently, about half of these patients receive chemotherapy, but it only slightly improves survival rates and can have harmful side effects, especially for those who don't need it.

Oxford Cancer Biomarkers Limited (OCB) has developed a new technology called OncoProg, which uses machine learning and image analysis to identify early-stage colon cancer patients who are likely to benefit from chemotherapy and those who are not. This study aims to integrate OncoProg into hospital routines to help doctors and patients make better decisions about chemotherapy after surgery, potentially improving the overall efficiency of the NHS.

Who can participate?
This study involves collecting data from patients with early-stage colon cancer who are undergoing routine pathology analysis at University Hospital Birmingham and its satellite sites in the West Midlands. You may be asked to participate if your tumour sample is being analysed as part of this routine care.

What does the study involve?
If you are part of this study, your tumour sample will be analysed using the OncoProg system as part of your routine care. The results from OncoProg will provide your doctors with additional information about your cancer to help decide whether chemotherapy is the right option for you. You won't need to do anything extra beyond your normal care, and the study will not change the treatment you receive unless your doctor discusses it with you.

What are the possible benefits and risks of participating?
The potential benefit of participating in this study is that it may provide your doctors with more precise information about your cancer, which could help you make a better-informed decision about chemotherapy. However, this will not necessarily lead to a change in your treatment plan, as the final decision will always be made by you and your doctor. There are no direct risks to you as a participant since the study uses your existing tumour sample and does not involve additional treatments.

Where is the study run from?
The study is being conducted at University Hospital Birmingham (UK), which will act as the main hub. Other sites in the West Midlands will also be involved in collecting data.

When is the study starting and how long is it expected to run for?
April 2023 to September 2026

Who is funding the study?
The study is funded by an AI in Health and Care Award from the Department of Health and Social Care (UK)

Who is the main contact?
Dr Susan Fotheringham, susan.fotheringham@oxfordbio.com

Contact information

Type(s)
Principal Investigator

Contact name
Prof David Kerr

ORCID ID
http://orcid.org/0000-0001-7811-6722

Contact details
Nuffield Division of Clinical and Laboratory Sciences | Level 4, Academic Block, John Radcliffe Infirmary, Headington
Oxford
United Kingdom
OX3 9DU
+44 300 304 7777
david.kerr@ndcls.ox.ac.uk

Type(s)
Principal Investigator

Contact name
Dr Victoria Kunene

Contact details
Queen Elizabeth Hospital, Mindelsohn Way
Birmingham

United Kingdom
B15 2GW
+44 121 371 3603
Victoria.Kunene@uhb.nhs.uk

Type(s)
Public, Scientific

Contact name
Dr Susan Fotheringham

ORCID ID
http://orcid.org/0000-0001-5440-8747

Contact details
1 Robert Robinson Avenue, The Oxford Science Park
The Oxford Science Park
Oxford
United Kingdom
OX4 4GA
+44 1865784742
susan.fotheringham@oxfordbio.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
330060

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 330060

Study information

Scientific Title
Prognostic value of ploidy and digital tumour-stromal morphometric analyses for guiding chemotherapy treatment for Stage II/III Colon Cancer Patients

Acronym
ONCOPROG_AI

Study objectives
Does the provision of the OncoProg test result inform the clinician/patient's decision about the uptake of adjuvant chemotherapy?

This study will:
Assess the differences, if any, in treatment recommendation for CRC Stage II and Stage IIIA patients, before and after the provision of OncoProg results
Demonstrate the health-economic benefit of adopting OncoProg as a tool for guiding chemotherapy treatment for CRC Stage II and Stage IIIA

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/03/2024, East of England REC (Equinox House, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 23/EE/0227

Study design
Multi-centre interventional operational feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Other, Treatment

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cancer: Stage II (T3/T4) or stage IIIA (T1-3N1) colorectal carcinoma (histological diagnosis)

Interventions
This study involves the use of the digital biomarker test OncoProg to assess the cancer recurrence risk of patients and modification of treatment pathways accordingly. The use of OncoProg is compared to SOC (no test).

This is a one-arm study in which all patients are introduced to the OncoProg test and given the option for this test to be used in their treatment planning. Once the patient has consented to enrolment in the study, their tumour tissue is processed to allow assessment using the OncoProg test. The OncoProg test is conducted on the processed tissue and the results of the test are recorded. The OncoProg results are then sent to the Oncologist for review alongside other SoC test results (as SoC patients will have a set of standard baseline blood tests to measure their full blood cell counts, blood clotting, kidney and liver function, etc). At this point, clinicians will be asked to record what adjuvant treatment they would aim to prescribe, based on the conventional information made available to them, e.g., standard morphological pathology data, mismatch repair status, performance status and comorbidities (other medical history). The oncologist will consider the OncoProg results alongside SoC test results and record whether

OncoProg test results affect their chemotherapy recommendations and if so what changes to recommendations would be made.

During the clinical appointment where the Oncologist and patient discuss treatment options, the treatment will be agreed upon based on evidence of SoC data. The OncoProg result will then subsequently be discussed by the patient and oncologist and the oncologist shall record if any change in treatment is agreed with the patient and record the nature of that change. The oncologist and the patient will then be asked to complete an acceptability questionnaire to record their views on the use of OncoProg for treatment decision-making.

The use of OncoProg is a one-off test before treatment is planned (observation i.e. no treatment after surgery as the patient is at low risk of recurrence or chemotherapy if the patient is at high risk of recurrence). The use of the OncoProg test results in treatment planning and the opinions of both the oncologist and patient will be recorded to achieve the study objectives. There is no planned follow-up once this information has been recorded.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OncoProg

Primary outcome measure
The treatment regimen decided upon after the OncoProg results are available is measured using the data captured on the case report form (CRF) about the agreed treatment regimen between the medical oncologist and the patient, which is documented in the post-OncoProg CRF

Secondary outcome measures
1. Demonstrate the health economic benefit of adopting OncoProg as a tool for guiding chemotherapy treatment for CRC Stage II and Stage IIIA measured using patient healthcare utilisation data/CRF data at the end of the study
2. Acceptability to patient and clinician measured using acceptability questionnaires at the end of the study

Overall study start date
01/04/2023

Completion date
30/09/2026

Eligibility

Key inclusion criteria

1. Stage II (T3/T4) or stage IIIA (T1-3N1) colorectal carcinoma (histological diagnosis)
2. Age >18 years
3. The patient is considered fit enough to be considered for fluoropyrimidine (FP) based systemic chemotherapy as treatment for colorectal cancer, in the adjuvant setting
4. In the Investigator's opinion, is able and willing to comply with all trial requirements and give clearly documented consent
5. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
270

Key exclusion criteria
1. Any known contraindications to 5FU based chemotherapy
2. Pregnancy or breast-feeding
3. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial
4. Rectal tumours that have been treated with chemo-radiotherapy prior to surgery
5. Patients that have been treated with chemotherapy prior to surgery

Date of first enrolment
02/09/2024

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Birmingham
Queen Elizabeth Hospital
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Walsall Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Sponsor information

Organisation
Oxford Cancer Biomarkers Ltd

Sponsor details
1 Robert Robinson Avenue, The Oxford Science Park
The Oxford Science Park
Oxford
England
United Kingdom
OX44GA
+44 1865784742
OncoProg@oxfordbio.com

Sponsor type
Industry

Website
https://www.oxfordbio.com/

Funder(s)

Funder type
Government

Funder Name
Department of Health and Social Care

Alternative Name(s)
Department of Health & Social Care, DH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.4	04/03/2024	02/09/2024	No	Yes
Participant information sheet	version 3.3	04/03/2024	02/09/2024	No	Yes
Protocol file	version 16.1	19/10/2023	02/09/2024	No	No