A study comparing cancer patients randomly assigned to be offered either genetic testing 'at home' or in hospital

Submission date	Recruitment status Recruiting	[X] Prospectively registered			
21/07/2023		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
26/07/2023	Ongoing Condition category	☐ Results			
Last Edited		Individual participant data			
03/10/2024	Cancer	Record updated in last year			

Plain English summary of protocol

Background and study aims

Patients who are diagnosed with womb, bowel, or ovarian cancer that fulfill NHS genetic testing criteria are recommended to have genetic testing to see if their cancer was related to an inherited gene alteration. Identifying carriers of alterations allows novel personalised cancer treatments, prevention of second cancers, and testing of family members for cancer screening and prevention. Genetic testing requires pre-test counselling to ensure patients are informed about the impact of having a genetic test and managing the result. This 'genetic counselling' has traditionally been provided by genetics services. However, it is now routinely being offered by cancer-treating teams in an approach called "mainstreaming". Currently, the demand for genetic counselling and testing is swiftly increasing and capacity constraints requires the development of new scalable cost and resource-efficient implementation models. This study will assess if pretest counselling and genetic testing can be done using a direct-to-patient model. Participants will receive genetic testing information on a smartphone app or website that they can access at home along with counselling support through a study telephone helpline. Those who agree to testing can consent via the app and perform testing at home with a saliva genetic testing kit delivered and returned by post. In the study this direct-to-patient approach is directly compared to the standard mainstreaming approach.

Who can participate?

Patients aged 18 years and over diagnosed with bowel, womb, or ovarian cancer who are eligible for NHS genetic testing

What does the study involve?

This study compares and evaluates the uptake of genetic testing using both approaches. The researchers also assess patient satisfaction, quality-of-life, and psychological outcomes following testing, using standardized or customized questionnaires over 1 year of follow-up. Clinician opinions will be elicited. Some patients will also be interviewed to assess attitudes, experiences, and impact on emotional wellbeing. An economic analysis will be undertaken to assess the cost-effectiveness of this approach for the NHS.

What are the possible benefits and risks of participating?

Patients that take part in the study will be offered genetic testing. Everyone who is offered genetic testing is given information about the potential risks or benefits of genetic testing. This may have implications for patients' cancer treatment, as they can be offered novel treatments which can improve outcomes. They can also opt for cancer prevention options to prevent other (second) cancers for themselves. Family members can also be tested and opt for screening or cancer prevention options.

Patients may be assigned to receive genetic testing information and genetic testing at home. They will not have to attend a hospital for this to take place. Taking part in this study will also help determine if this direct-to-patient approach of offering genetic testing is as acceptable for patients as standard genetic testing in clinics. Genetic testing is offered as part of standard NHS cancer care. Some people who receive positive genetic test results may feel frightened, sad or upset about their test result. A positive result may mean that patients find out that they have an increased risk of developing other cancers. This may be a result that they were not expecting.

Where is the study run from?
Wolfson Institute of Population Health, Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for? January 2022 to October 2028

Who is funding the study?

- 1. GlaxoSmithKline (UK)
- 2. Barts Charity (UK)
- 3. North East London Cancer Alliance (UK)
- 4. North Central London Cancer Alliance (UK)

Who is the main contact?

Prof. Ranjit Manchanda, bartsctu-detect-2@gmul.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-two-different-ways-of-carrying-out-genetic-testing-for-people-with-cancer-detect

Contact information

Type(s)

Principal investigator

Contact name

Prof Ranjit Manchanda

ORCID ID

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

319066

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 319066, CPMS 57783

Study information

Scientific Title

Direct-to-patient testing at cancer diagnosis for precision prevention-2

Acronym

DETECT-2

Study objectives

Patients at colorectal, endometrial, or ovarian cancer diagnosis have equal genetic testing uptake when offered direct-to-patient genetic testing at cancer diagnosis when compared to standard of care (mainstream genetic testing by members of cancer-treating teams)

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 29/08/2023, London - Brighton & Sussex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8202; brightonandsussex.rec@hra.nhs.uk), ref: 23/LO/0677

Study design

National multicentre two-arm interventional randomized control trial

Primary study design

Interventional

Study type(s)

Other, Quality of life, Efficacy

Health condition(s) or problem(s) studied

Patients diagnosed with colorectal, endometrial, or ovarian cancer eligible for genetic testing for cancer susceptibility gene variants

Interventions

Eligible patients undergo block randomisation (1:1, stratified by cancer type) at recruitment to one of the two study arms:

1. Direct-to-patient testing: Patients will be provided information about genetic testing on a web-app decision aid. This decision aid will be accessible on smartphones, tablets, and web browsers and provide information about genetic testing, how it is performed, the possible results, and potential impacts. The web app will include the consent form for genetic testing allowing patients to accept or decline genetic testing electronically.

Patients consenting to genetic testing will receive a sample collection kit in the post, provide their sample at home using the saliva-collection kit, and post it back to the genetic testing laboratory to perform the testing.

Results will be returned by post and email, and patients will be supported throughout the entirety of this pathway by a telephone helpline staffed by study counsellors experienced in genetic counselling. Patients with positive or uncertain results from genetic testing will be given post-test counselling. Participating sites will refer these patients to their local genetics service(s) as per standard NHS practice/care followed.

2. Standard of care: Patients will receive pre-test counselling from a non-genetics clinician with consent for genetic testing, blood sample collection, and return of results undertaken in clinic as per routine hospital practice.

Intervention Type

Other

Primary outcome(s)

Uptake of genetic testing between the direct-to-patient genetic testing arm versus standard mainstreaming. Uptake of genetic testing will be assessed by equivalency at the end of the study (each event is recorded at decision to test and equivalence is calculated at the end of the study).

Key secondary outcome(s))

- 1. Decision satisfaction or regret assessed by the 5-item Decision Regret Scale (O'Connor) assessed up to 1 year following return of genetic test results
- 2. Mental health and emotional outcomes measured by the Hospital Anxiety and Depression Scale, 1-item "I am satisfied with the decision I have made" 5-point Likert scale, Impact of Events Scale, and Multidimensional Impact of Cancer Risk Assessment measured at baseline (if relevant) and up to 1 year following the return of genetic test results.
- 3. Participant quality-of-life assessed by EuroQol EQ-5D-5L questionnaire, validated cancer-specific and general cancer EORTC questionnaires at baseline and after genetic testing up to 1 year following the return of genetic test results
- 4. Attitudes, experiences, and impact on emotional health assessed by semi-structured qualitative interviews at 1-6 months after receiving the genetic testing result
- 5. Decision aid and telephone helpline use in direct-to-patient testing pathway assessed by participant usage statistics collected by the web app and telephone helpline usage case report forms for all participants in the DTP arm at decision to test, 21 days post result and 6 months post result
- 6. Variant prevalence measured by the number of pathogenic/likely-pathogenic variants/variant

of uncertain significance detected divided by the number of people undergoing genetic testing at the end of the study

- 7. Cost-effectiveness of both testing approaches will be assessed by incremental cost-effectiveness ratio (ICER/QALY) between the two study arms assessed against the willingness-to-pay threshold stipulated by NICE (£20,000-30,000/QALY) at the end of the study 8. Clinician experience of direct-to-patient testing pathway measured using a bespoke clinician
- 8. Clinician experience of direct-to-patient testing pathway measured using a bespoke clinician questionnaire administered to participating clinicians once a site is set up and operating

Completion date

01/10/2028

Eligibility

Key inclusion criteria

1. Adults diagnosed with endometrial cancer or colorectal cancer fulfilling NHS clinical genetic testing criteria for mismatch repair genes based on clinical or histo-pathological molecular profile

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2. Adults diagnosed with high-grade epithelial ovarian cancer fulfilling NHS clinical genetic testing criteria

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Current exclusion criteria as of 09/05/2024:

- 1. Patients who have had previous genetic testing for Lynch Syndrome, OC, or CRC genes
- 2. Patients whose family has a known pathogenic variant in a cancer susceptibility gene, which is part of the panel the patient is eligible for undergoing testing.
- 3. Unable to provide informed consent

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- 1. Patients who have had previous genetic testing for Lynch Syndrome, or OC genes
- 2. Patients whose family has a known pathogenic variant in one of the following genes: BRCA1, BRCA2, RAD51C, RAD51D, BRIP1, PALB2, MLH1, MSH2, MSH6, PMS2
- 3. Unable to provide informed consent

Date of first enrolment 25/04/2024

Date of final enrolment 30/09/2026

Locations

Countries of recruitment

United Kingdom

England

Northern Ireland

Scotland

Study participating centre Barts Health NHS Trust

The Royal London Hospital 80 Newark Street London United Kingdom E1 2ES

Study participating centre University College London Hospitals NHS Foundation Trust

250 Euston Road London United Kingdom NW1 2PG

Study participating centre London North West University Healthcare NHS Trust

Northwick Park Hospital Watford Road Harrow United Kingdom HA1 3UJ

Study participating centre Nottingham University Hospitals NHS Trust

Trust Headquarters Queens Medical Centre Derby Road Nottingham United Kingdom NG7 2UH

Study participating centre University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters Marlborough Street Bristol United Kingdom BS1 3NU

Study participating centre Imperial College Healthcare NHS Trust

The Bays St Marys Hospital South Wharf Road London United Kingdom W2 1BL

Study participating centre Barking, Havering and Redbridge University Hospitals NHS Trust

Queen's Hospital Rom Valley Way Romford United Kingdom RM7 0AG

Study participating centre University Hospital Southampton NHS Foundation Trust Southampton General Hospital Tremona Road

Southampton United Kingdom SO16 6YD

Study participating centre Sandwell and West Birmingham Hospitals NHS Trust

City Hospital Dudley Road Birmingham United Kingdom B18 7QH

Study participating centre Norfolk & Norwich University Hospitals NHS Foundation Trust

Colney Lane Colney Norwich United Kingdom NR4 7UY

Study participating centre

University Hospitals Sussex NHS Foundation Trust

Worthing Hospital Lyndhurst Road Worthing United Kingdom BN11 2DH

Study participating centre

University Hospitals Dorset NHS Foundation Trust

Management Offices Poole Hospital Longfleet Road Poole United Kingdom BH15 2JB

Study participating centre Portsmouth Hospitals University NHS Trust

Queen Alexandra Hospital Portsmouth United Kingdom PO6 3LY

Study participating centre Maidstone and Tunbridge Wells NHS Trust

The Maidstone Hospital Hermitage Lane Maidstone United Kingdom ME16 9QQ

Study participating centre East Kent Hospitals University NHS Foundation Trust

Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre Oxford University Hospitals NHS Foundation Trust

John Radcliffe Hospital Headley Way Headington Oxford United Kingdom OX3 9DU

Study participating centre Manchester University NHS Foundation Trust

Cobbett House Oxford Road Manchester United Kingdom M13 9WL

Study participating centre NHS Grampian Summerfield House 2 Eday Road Aberdeen

United Kingdom AB15 6RE

Study participating centre Belfast Health and Social Care Trust

Trust Headquarters A Floor - Belfast City Hospital Lisburn Road Belfast United Kingdom BT9 7AB

Study participating centre NHS Lothian

Waverley Gate 2-4 Waterloo Place Edinburgh United Kingdom EH1 3EG

Study participating centre Somerset NHS Foundation Trust

Trust Management Lydeard House Musgrove Park Hospital Taunton United Kingdom TA1 5DA

Study participating centre South Tyneside and Sunderland NHS Foundation Trust

Sunderland Royal Hospital Kayll Road Sunderland United Kingdom SR4 7TP

Study participating centre County Durham and Darlington NHS Foundation Trust Darlington Memorial Hospital Hollyhurst Road

Darlington United Kingdom DL3 6HX

Study participating centre University Hospitals of Derby and Burton NHS Foundation Trust

Royal Derby Hospital Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre Cardiff and Vale NHS Trust

Cardigan House University Hospital of Wales Heath Park Cardiff United Kingdom CF14 4XW

Study participating centre University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

Study participating centre North Bristol NHS Trust

Southmead Hospital Southmead Road Westbury-on-trym Bristol United Kingdom BS10 5NB

Sponsor information

Organisation

Queen Mary University of London

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Industry

Funder Name

GlaxoSmithKline

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

Barts Charity

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

North East London Cancer Alliance

Funder Name

North Central London Cancer Alliance

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Ranjit Manchanda (bartsctu-detect-2@qmul.ac.uk)

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes