

SYMPLIFY – assessing a multi-cancer early detection test in individuals referred with signs and symptoms of cancer

Submission date 24/06/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/08/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/02/2026	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cancer is easier to treat if it is diagnosed early. The NHS has developed rapid referral pathways to allow cancers to be diagnosed earlier, but this requires us to run tests on a lot more people than turn out to have cancers. This creates worry for some people, may not be the most efficient use of NHS resources, a significant proportion of cancers are diagnosed via other routes, often when it is too late to cure them.

We know that the DNA from cancers can be detected in the blood early on and want to use this fact to detect cancers earlier than existing pathways. In this study we want to check the performance of one such multi-cancer early detection (MCED) test.

Who can participate?

People sent to one of 5 rapid referral pathways by their GP because they have symptoms that might be due to cancer.

What does the study involve?

People taking part in the study will have their diagnostic test(s) in the normal way, but will also give a blood sample and permission for us to check their health records later to see if they were diagnosed with cancer and what appointments and other tests they had.

At the end of the study, having tested the blood with the MCED test, we will understand more about how well it works in this group of people, and expect that this will help us to design another trial where we check how to use the test to decide who needs rapid referral to look for a possible cancer and what tests to use following a positive MCED result.

What are the possible benefits and risks of participating?

If someone participates, they will be contributing to important research into how to detect cancer early. This may benefit people in the future. If the Galleri™ test turns out to detect cancer early, we may be able to treat more cancers more successfully

We will do everything we can to make sure participants in this study don't experience any harm. They will need to give a blood sample. Although this process is generally safe, they may experience discomfort or light-headedness, and there is a small risk of infection. If blood needs

to be taken as part of their hospital care, the research blood sample will be taken at the same time.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
February 2021 to November 2022

Who is funding the study?
Grail Bio UK Ltd

Who is the main contact?
Sarah Pearson, octo-symplify@oncology.ox.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Sarah Pearson

ORCID ID
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
299310

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

OCTO_105

Central Portfolio Management System (CPMS)

49672

Study information

Scientific Title

SYMPLIFY – Observational study to assess a multi-cancer early detection test in individuals referred with signs and symptoms of cancer

Acronym

SYMPLIFY

Study objectives

To evaluate the performance of a multi-cancer early detection (MCED) test for the detection of invasive cancer and the identification of cancer signal origin

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/06/2021, London Central REC (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8225; londoncentral.rec@hra.nhs.uk), ref: 21/LO/0456)

Study design

Prospective observational multi-centre cohort

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Early detection of cancer

Interventions

Participants will be asked to give consent and provide a single blood sample during one visit to hospital. After that the participants have no further direct involvement, all follow-up is through collection of data. We collect data on participants at 3 and 12 months from registration into the study to find out whether or not they had a diagnosis of cancer. (We will also do a check at 9 months to collect any data that was not available at the 3 month timepoint).

Intervention Type

Other

Primary outcome(s)

At an interim analysis within 3 months of complete enrolment with complete analysis at 12 months of enrolment, measured by comparing blood sample analysis and patient notes:

1. Positive Predictive Value
2. Negative Predictive Value
3. Sensitivity
4. Specificity
5. Cancer signal origin accuracy

Key secondary outcome(s)

At an interim analysis within 3 months of complete enrolment with complete analysis at 12 months of enrolment, measured by comparing blood sample analysis and patient notes:

1. Concordance between referral pathway selected by GP and CSOs identified by MCED
2. Number of true positives/number of patients referred within each referral pathway

Completion date

30/11/2022

Eligibility

Key inclusion criteria

1. Participants referred to an RDC or relevant 2WW pathway to rule a cancer diagnosis in or out will be invited to participate in the study.
2. Willing and able to give informed consent for participation in the study.
3. Male or Female, aged 18 years or above.
4. Referred to a RDC or a gynae, lung, upper GI or lower GI cancer 2WW pathway.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Total final enrolment

6238

Key exclusion criteria

1. Has a history of invasive or haematological malignancy diagnosed within the previous 3 years.
2. Has undergone definitive treatment for invasive or haematological malignancy in the last 3 years (adjuvant hormone therapy is permissible in this context).
3. Is taking cytotoxic or demethylating agents such as methotrexate.

4. Previous or current participation in another GRAIL study. "Participation" is defined as having signed consent and provided a blood sample.

Date of first enrolment

05/07/2021

Date of final enrolment

30/11/2021

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre

Southampton General Hospital

University of Southampton and University Hospital Southampton NHS Foundation Trust

Tremona Road

Southampton

England

SO16 6YD

Study participating centre

Buckinghamshire Healthcare NHS Trust

Mandeville Road

Aylesbury

England

HP21 8AL

Study participating centre

Churchill Hospital

Oxford University Hospitals NHS Foundation Trust

Old Road

Headington

Oxford

England

OX3 7LE

Study participating centre

Royal Berkshire Hospital

Royal Berkshire NHS Foundation Trust
London Road
Reading
England
RG1 5AN

Study participating centre**Basildon and Thurrock University Hospital**

Mid and South Essex NHS Foundation Trust
Nethermayne
Basildon
England
SS16 5NL

Study participating centre**Torbay & South Devon Foundation Trust**

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Torquay
England
TQ2 7AA

Study participating centre**Royal Cornwall Hospital**

Royal Cornwall Hospital NHS Trust
Truro
England
TR1 3HD

Study participating centre**Royal Free Hospital**

Royal Free London NHS Foundation Trust
Pond Street
London
England
NW3 2QG

Study participating centre**University College London Hospital**

University College London Hospitals NHS Foundation Trust
250 Euston Road

London
England
NW1 2PG

Study participating centre
North Middlesex University Hospital NHS Trust

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London
England
N18 1QX

Study participating centre

York Hospital

York & Scarborough Teaching Hospitals NHS Foundation Trust

York

England

YO31 8HE

Study participating centre

Hull University Teaching Hospitals NHS Trust

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Hull

England

HU16 5JQ

Study participating centre

Wales - multiple hospitals under one lead site (Velindre NHS Trust)

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Cardiff

Wales

CF14 2TL

Study participating centre

Chelsea and Westminster Hospital NHS Foundation Trust

Chelsea & Westminster Hospital

369 Fulham Road

London

England

SW10 9NH

Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Industry

Funder Name

Grail Bio UK Ltd

Results and Publications

Individual participant data (IPD) sharing plan

All requests for secondary use of data should be directed to cancer@phc.ox.ac.uk.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/06/2023	26/06/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Validity and timeliness comparison of cancer data obtained on-site during SYMPLIFY with data from English and Welsh national cancer registries	09/10/2024	17/10/2024	Yes	No
Plain English results			08/12/2025	No	Yes
Preprint results	Two-year follow-up	21/10/2025	12/02/2026	No	No
Study website		11/11/2025	11/11/2025	No	Yes