ISRCTN91431511 https://doi.org/10.1186/ISRCTN91431511

# Does screening with the Galleri test in the NHS reduce the likelihood of a late-stage cancer diagnosis?


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| **Submission date** 02/09/2021 | **Recruitment status** No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date** 16/09/2021 | **Overall study status** Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited** 13/02/2025 | **Condition category** Cancer | [_] Individual participant data<br>[X] Record updated in last year |


## Plain English summary of protocol

Background and study aims
The Galleri test is a new test that looks for potential signs of cancer in a blood sample. The test can find many different types of cancer but cannot find all cancers. The trial aims to see if using the Galleri test alongside standard cancer testing in the NHS can help to find cancers at an early stage when they are easier to treat.

Who can participate?
Individuals aged 50 - 77 years who meet the eligibility criteria and live in certain parts of England.

What does the study involve?
Participants who meet the criteria for the trial and who decide to take part will attend study visits at mobile clinics. At each visit, participants will give a blood sample and fill in a survey. Participants will be asked to attend study visits a total of three times over two years.
Half the people in the trial will be in the 'test group.' This means that their blood sample will be tested using the Galleri test. The other half will be in a 'control group' and their blood will be safely stored but not immediately tested with the Galleri test. Participants will not be told which group they are in. Only participants who are in the test group and who have a positive test result will be told. Anyone with a positive test result will have follow-up tests at a local hospital to see if they actually have cancer.

What are the possible benefits and risks of participating?
Participants may not benefit directly from taking part in this trial as there is a 50% chance their blood sample will not be tested immediately. The majority of participants will not benefit during the trial, but will be contributing to important research that may benefit people in the future.
Because the Galleri test is a blood test, participants will need to give blood samples. Although giving a blood sample is generally very safe, there are some possible risks including slight bleeding, bruising, discomfort, lightheadedness or, in rare cases, infection and fainting.
There is a potential risk related to a false positive test result. Participants may experience anxiety or distress because the Galleri test may give a wrong result. If the test detects a cancer signal and no cancer is found by the doctor, the participant may have had follow-up tests that

were unnecessary.
There is a potential risk related to an incorrect cancer signal origin (ie. tumour type) on the test result. Participants may have to have additional tests to see if they have cancer.
There is a potential risk of over diagnosis, meaning the diagnosis of a cancer that would not have caused a problem.
There are potential risks associated with the COVID-19 pandemic.

Where is the study run from?
The Cancer Research UK and King's College London Cancer Prevention Trials Unit (UK)

When is the study starting and how long is it expected to run for?
July 2021 to February 2026

Who is funding the study?
GRAIL Bio UK Ltd

Who is the main contact?
Cherry Paice, info@nhs-galleri.org

### Study website
https://www.nhs-galleri.org

## Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number
293034

### ClinicalTrials.gov number
NCT05611632

### Secondary identifying numbers
GRAIL-009, IRAS 293034, CPMS 49043

# Study information

### Scientific Title
A randomised controlled trial to assess the clinical utility of a multi-cancer early detection (MCED) test for population screening in the United Kingdom (UK) when added to standard of care.

### Acronym
NHS-Galleri

### Study objectives
The study aims to establish whether a multi-cancer early detection test applied before individuals present to a physician with cancer symptoms can meaningfully reduce the stage at which cancers are diagnosed when used alongside NHS standard of care.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 01/07/2021, Wales REC 1 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)7787 371748; Wales.REC1@wales.nhs.uk), ref: 21/WA/0141

### Study design
Pragmatic prospective randomized controlled trial blinded at the time of randomization

### Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Community

## Study type(s)
Screening

## Participant information sheet
https://www.nhs-galleri.org/downloads/participant-information-sheet

## Health condition(s) or problem(s) studied
Multi cancer early detection in people without symptoms

## Interventions
A prospective, randomised, controlled trial to assess the performance and clinical utility of a multi-cancer early detection test for population screening in the UK when added to standard of care.

Randomisation will be to the intervention arm, with blood collection and evaluation of the test or to the control arm, where blood samples are collected and will be stored for potential future evaluation but participants do not receive test results. All participants should continue to participate in routine NHS screening.
Unless diagnosed with cancer, participants in both arms will be asked to return for annual visits at approximately 12 and 24 months.
All participants whether test positive, test negative, or not tested will be followed for cancer and associated outcomes via NHS dataset linkages.

Participants in the intervention arm who test positive will be referred for standard of care investigations and treatment in the NHS.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
-

## Primary outcome measure
1. Incidence and stage at diagnosis for cancer types that are stageable (e.g., with available staging systems) measured using patient records.
Cancer is defined as any of the following cancers:
Invasive solid cancer, excluding basal cell carcinoma and squamous cell carcinoma of the skin
Haematologic malignancies, including lymphoma, lymphoid leukemia, myeloma/plasma cell neoplasm, myeloid neoplasms (including myelodysplastic and myeloproliferative neoplasms with behaviour code 3 based on ICD-O-3.2).
The following cancer types are not routinely staged and will therefore be excluded from the analysis of this primary objective: brain cancers, leukemias, cancers of unknown primary.

## Secondary outcome measures

Current secondary outcome measures as of 13/02/2025:

Measured using patient records:
1. Incidence and stage at diagnosis for cancer types that are stageable (e.g., with available staging systems) at other timepoints.
2. Cancer-specific mortality up to 8 years after randomization

Safety endpoints (measured throughout the study):
3. Among all test positive cases, number of follow-up procedures and number of invasive procedures (including all biopsies, surgical interventions, bronchoscopy, thoracoscopy and endoscopy) to achieve diagnostic resolution (i.e. cancer diagnosis, non-cancer diagnosis, or no diagnosis and discharge from the diagnostic follow-up)
4. Number and type of invasive procedures performed in false positive cases;
5. Number of complications and deaths resulting from diagnostic procedures;
6. Radiation exposure measured in mSv per participant due to test result-directed evaluations;
7. Among all test positive cases, psychological impact, including anxiety, measured after Galleri test, after diagnostic resolution and at 12 months post testing using the short-form State Trait Anxiety Index-6 (STAI), a six-item validated measure of state anxiety.

Healthcare resource utilisation endpoints:
8. The data collected may be used to conduct future exploratory economic analyses, and will include: Number and types of medical encounters and cancer-specific diagnostic and treatment procedures, including clinical lab visits, imaging tests, invasive tests, and clinic visits.

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Previous secondary outcome measures:

Measured using patient records:
1. Incidence and stage at diagnosis for cancer types that are stageable (e.g., with available staging systems) at other timepoints.
2. Mortality at 16-18 months of follow-up for a pre-specified group of cancer types, at years 3 and 6 after the last study visit, and at 7-years post-randomisation based on cancers diagnosed within an average of 40-42 months of randomisation.

Safety endpoints (measured throughout the study):
3. Among all test positive cases, number of follow-up procedures and number of invasive procedures (including all biopsies, surgical interventions, bronchoscopy, thoracoscopy and endoscopy) to achieve diagnostic resolution (i.e. cancer diagnosis, non-cancer diagnosis, or no diagnosis and discharge from the diagnostic follow-up)
4. Number and type of invasive procedures performed in false positive cases;
5. Number of complications and deaths resulting from diagnostic procedures;
6. Radiation exposure measured in mSv per participant due to test result-directed evaluations;
7. Among all test positive cases, psychological impact, including anxiety, measured after Galleri test, after diagnostic resolution and at 12 months post testing using the short-form State Trait Anxiety Index-6 (STAI), a six-item validated measure of state anxiety.

Healthcare resource utilisation endpoints:
8. The data collected may be used to conduct future exploratory economic analyses, and will include: Number and types of medical encounters and cancer-specific diagnostic and treatment procedures, including clinical lab visits, imaging tests, invasive tests, and clinic visits.

### Overall study start date
01/07/2021

### Completion date
28/02/2026

## Eligibility

### Key inclusion criteria
1. Participants must be at 50-77 years of age, inclusive, at the time of data extraction from NHS datasets or GP records used to identify potential participants; and
2. Capable of giving signed and legally effective informed consent, which includes compliance with the requirements and restrictions listed in the Informed Consent Form (ICF) and in this protocol. Consent provided by a legally authorised representative is not permitted in this protocol.

### Participant type(s)
Healthy volunteer

### Age group
Adult

### Lower age limit
50 Years

### Upper age limit
77 Years

### Sex
Both

### Target number of participants
140,000

### Total final enrolment
142318

### Key exclusion criteria
1. Previous or current participation in another GRAIL-sponsored study.
2. Personal history of invasive cancer or haematologic malignancy, diagnosed within the three years prior to expected enrolment date. Note: Individuals with a diagnosis of non-melanoma skin cancer and prostate cancer patients whose only treatment is active surveillance are NOT excluded
3. Definitive treatment for invasive cancer or haematologic malignancy within the 3 years prior

to expected enrolment date, including adjuvant hormone therapy for cancer (e.g. for breast or prostate cancer).
4. Currently taking demethylating or cytotoxic agents for any condition.
5. Undergoing current investigation for suspected cancer, defined as having been referred to a two week wait clinic or undergoing investigations at an RDC or other clinic with a stated suspicion of cancer.
6. Currently on a palliative care pathway.

### Date of first enrolment
31/08/2021

### Date of final enrolment
30/06/2022

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**EMS Healthcare**
The Refinery
South Road
Ellesmere Port
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## Sponsor information

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GRAIL Bio UK Ltd.

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### Sponsor type
Industry

**Website**
https://grail.com/

# Funder(s)

**Funder type**
Industry

**Funder Name**
GRAIL Bio UK Ltd

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer reviewed journal.

**Intention to publish date**
28/02/2026

**Individual participant data (IPD) sharing plan**
The current data sharing plans for this 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? |
|---|---|---|---|---|---|
| Protocol article | | 01/10/2022 | 17/10/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |