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Accelerated community multi cancer diagnostic evaluation platform

Submission date
11/08/2026

Recruitment status
Recruiting

Registration date
23/09/2026

Overall study status
Ongoing

Last Edited
23/09/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Many people visit their GP with symptoms such as abdominal pain, loss of appetite, bloating, nausea or unexplained weight loss. These symptoms are common and are often caused by conditions other than cancer, but they can sometimes be a sign of cancer. Because these symptoms can have many different causes, it can be difficult for GPs to decide which patients should be referred to hospital for specialist cancer tests.
Multi-cancer blood tests are new types of blood tests that look for signals associated with several different types of cancer. They could potentially help GPs decide which patients need further investigation. Before these tests can be used routinely in the NHS, researchers need to understand how accurately they identify people who do and do not have cancer.
The ARMADILO study aims to assess several multi-cancer blood tests in people aged 50 years or over who are having NHS blood tests because they have symptoms that could have a number of causes, including cancer. The researchers will compare the multi-cancer test results with information from participants' NHS health records to assess how accurately the tests identify people who are diagnosed with cancer.
This is an observational study, so taking part will not change a participant's medical care. The multi-cancer test results will not be given to participants nor their GPs and will not be used to make decisions about care because the accuracy of the tests is not yet known. Participants will continue to receive their usual NHS investigations and care.

Who can participate?
People may be able to take part if they:
1. Are aged 50 years or over
2. Are having a blood test in NHS primary care to investigate at least one of the following symptoms: abdominal pain, loss of appetite, bloating, nausea or weight loss
3. Are willing and able to give informed consent; and
4. Are willing and able to provide a blood sample for the research.
People cannot take part if they have already joined the ARMADILO study, or if they have had certain invasive cancers or cancers of the blood, bone marrow or lymphatic system, or definitive treatment for these cancers, within the previous three years. Some treatments, such as adjuvant hormone therapy, are allowed.

What does the study involve?
People who decide to take part will have one study visit. Where possible, this will take place at the same time as their usual NHS appointment for a blood test. In some areas, the study blood sample may instead be taken at the participant's home or another suitable community location. Participants will be asked to give one blood sample of up to 80 ml, answer some questions about themselves and their health, and give permission for researchers to obtain information from their medical records, including GP, hospital and central NHS records.
There are no further routine study visits. Participants' health records will be followed for at least 12 months to find out whether they are diagnosed with cancer. Participants will also be asked for permission for their records to potentially be followed for up to 5 years to investigate longer-term cancer and non-cancer outcomes.
The donated blood will be used to assess different multi-cancer tests. Participants and their GPs will not receive the results of these tests.
Some participants may also be invited to take part in an interview about their experience of the study. This will help the researchers understand how acceptable and practical the study procedures are and whether there are barriers that make it more difficult for some groups of people to take part.

What are the possible benefits and risks of participating?
There is no expected direct medical benefit to people who take part. In particular, taking part will not provide an earlier diagnosis or additional information about the cause of a participant's symptoms because the multi-cancer test results will not be returned. Participants' normal NHS investigations and care will continue regardless of whether they take part.
The information collected may help researchers determine whether multi-cancer blood tests could be useful in the NHS in the future. If suitable tests are identified and subsequently shown to work in further studies, they could potentially help GPs decide which patients need specialist cancer investigations and contribute to earlier diagnosis for future patients.
The main physical risks are those associated with having blood taken. These include temporary discomfort, bruising or light-headedness and a small risk of infection. Where possible, the research blood will be collected at the same time and using the same needle as the participant's routine NHS blood test, although in some circumstances an additional blood-taking appointment may be needed.

Where is the study run from?
The study is being led by researchers at the University of Oxford, Nuffield Department of Primary Care Health Sciences (UK). Recruitment will take place across approximately 132 primary care sites. The study is sponsored by the University of Oxford and is coordinated through the Oxford Collaborative Clinical Trials Unit.

When is the study starting and how long is it expected to run for?
October 2026 to September 2030

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR), Efficacy and Mechanism Evaluation programme (UK).

Who is the main contact?
ARMADILO Study Team, armadilo_pcctu@phc.ox.ac.uk

Contact information

Type(s)
Principal investigator, Scientific

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Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
348402

Central Portfolio Management System (CPMS)
64367

National Institute for Health and Care Research (NIHR)
169172

Study information

Scientific Title
AcceleRated community Multi cAncer DIagnostic evaLuatiOn platform (ARMADILO)

Acronym
ARMADILO

Study objectives
Primary objective:
To evaluate the overall performance of individual multi-cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer

Secondary objectives:
1. To evaluate the performance of individual multi cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer, by test result, cancer type, and cancer stage
2. To evaluate the performance of individual multi cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer, by patient characteristics and symptom cluster
3. To calculate the performance of combinations of multi-cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer, by test, result cancer type, cancer stage, patient characteristics, and symptom cluster
4. To test whether sequencing multi-cancer tests in symptomatic patients attending primary care leads to superior performance accuracy for newly-diagnosed invasive cancer to individual multi-cancer tests
5. To evaluate that recruitment is inclusive and representative of the eligible practice population (internal pilot)
6. Use qualitative methods to explore how practice staff and patient participants experience the study processes, including recruitment and participation
7. To compare the characteristics of participants that are selected by GPs with those that are identified from simple or risk algorithm searches of the electronic health record

Exploratory objectives:
1. To investigate if the addition of patient characteristics, symptoms, and blood test results optimise the performance of the multi-cancer tests
2. To model the potential the consequence of delayed ascertainment of the reference standard on cancer stage
3. To investigate the impact of pre-analytical factors on multi-cancer test performance
4. To assess the potential cost-effectiveness of adding the test to the cancer diagnostic process

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/09/2026, North West - Greater Manchester (GM) South Research Ethics Committee (HRA RES Centre Manchester 3rd Floor 3 Piccadilly Place London Road, Manchester, M1 3BN, United Kingdom; +44 (0)207 104 8014; gmsouth.rec@hra.nhs.uk), ref: 26/NW/0231

Primary study design
Observational

Study design
Observational cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cancer

Interventions
This is a single-arm prospective observational multicentre cohort study.

Potential participants will be identified either opportunistically when they see their GP or through regular searches of recent presentations at the GP practice. Eligible patients will be forwarded the Participant Information Leaflet and consent will be documented prior to any study blood draw and baseline data collection taking place.

Participants will be asked to donate up to 80 ml of blood and this blood will be collected as an addition to their NHS phlebotomy appointment however a separate study only blood draw will be permitted. Some baseline data (e.g., smoking status) will also be collected from participants. Participants will be asked to consent to their medical records being followed up via data linkage for a maximum of 5 years after they enter the study in order to ascertain the cause of their symptoms (cancer yes/no) at 12 month timepoint. Participants will have no direct follow up after the initial study visit. Longer data linkage is requested in the event 12-month timepoint analysis prompts the need for further follow up.

Multi-cancer diagnostic testing will be run retrospectively and results will not be returned to either participants or their GP. This will be explicitly stated as part of the Participant Information Leaflet. Participants will follow standard NHS pathways for any necessary investigations.

As part of our commitment to ensuring inclusive recruitment we will conduct an internal pilot and assess recruitment at 9 months to ensure participants are representative of the practice population. Study protocol and participant facing materials may be amended based on the findings of the internal pilot.

Following recruitment completion a retrospective Data Utility Comparison Study (DUCkS) will be conducted to assesses the future feasibility of data driven recruitment.

Intervention Type
Other

Primary outcome(s)
1. The overall performance of individual multi-cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer, measured using positive predictive value, negative predictive value, sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio at 12 months post recruitment

Key secondary outcome(s)
1. The performance of individual multi-cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer, by test result, cancer type, and cancer stage, measured using positive predictive value, negative predictive value, sensitivity, specificity,

positive likelihood ratio, negative likelihood ratio, and area under the curve at 12 months post recruitment
2. The performance of individual multi-cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer, by patient characteristics and symptom cluster, measured using positive predictive value, negative predictive value, sensitivity, specificity, positive likelihood ratio, and negative likelihood ratio at 12 months post recruitment
3. The performance of combinations of multi-cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer, by test, result cancer type, cancer stage, patient characteristics, and symptom cluster, measured using positive predictive value, negative predictive value, sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and area under the curve at 12 months post recruitment
4. Performance accuracy of sequencing multi-cancer tests in symptomatic patients attending primary care for newly-diagnosed invasive cancer compared to individual multi-cancer tests, measured using positive predictive value, negative predictive value, sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, and area under the curve at 12 months post recruitment
5. Internal pilot: whether recruitment is inclusive and representative of the eligible practice population, assessed using baseline demographic characteristics of participants recruited at site, baseline demographic characteristics of participants eligible for recruitment at site, recruitment rates at site and study level, and screening log review to identify reasons for declining participation/withdrawal at 9 months of recruitment
6. How practice staff and patient participants experience the study processes, including recruitment and participation, assessed using qualitative interviews with practice staff and patient participants and ethnographic observation of study processes at 6 to 18 months
7. The characteristics of participants that are selected by GPs compared with those that are identified from simple or risk algorithm searches of the electronic health record, assessed using baseline demographic characteristics of recruited patients and all practice patients at 12, 18 and 24 months of recruitment

Completion date
01/09/2030

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent for participation in the study
2. Aged 50 years or above
3. Having a blood test in NHS primary care for the investigation of at least one of the following non-specific symptoms: abdominal pain, appetite loss, bloating, nausea, weight loss
4. Willing and able to donate a blood sample for research

Study participants for the qualitative component:
1. Practice staff involved in delivering the study at sites including practice managers, GPs, nurses, receptionists and other practice staff
2. Patient participants: same criteria as for main study, but interviews may also include carers and /or family members involved in their care

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
50 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previously enrolled in this study
2. A history of invasive or haematological malignancy (cancers affecting blood, bone marrow and lymphatic system) diagnosed within the past 3 years
3. Has undergone definitive treatment for invasive or haematological malignancy in the past 3 years (adjuvant hormone therapy is permissible in this context)

Date of first enrolment
15/10/2026

Date of final enrolment
01/10/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North East and North Cumbria RRDN
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre
Yorkshire and Humber RRDN
St James's University Hospital
Beckett Street

Leeds
England
LS9 7TF

Study participating centre
North West RRDN
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
West Midlands RRDN
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
East of England RRDN
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre
North London RRDN
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
South London RRDN
St Thomas' Hospital
Westminster Bridge Road

London
England
SE1 7EH

Study participating centre
South Central RRDN
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
South East RRDN
Egerton Road
Guildford
England
GU2 7XX

Study participating centre
South West Central RRDN
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
South West Peninsula RRDN
Royal Devon University NHS FT
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
East Midlands RRDN
Leicester Royal Infirmary
Infirmary Square

Leicester
England
LE1 5WW

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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