ISRCTN17299125 https://doi.org/10.1186/ISRCTN17299125

Investigating the enlighten multi-cancer early detection test

Submission date 28/01/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 05/02/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 06/03/2026	**Condition category** Cancer	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Cancer remains the leading cause of death in the UK. If found at its earliest stage, patients are 5-10 times more likely to survive their diagnosis for 5 years, highlighting the importance of developing new early detection methods for cancer to increase patient survival rates, provide greater treatment options and reduce strain on the NHS. MODERNISED aims to evaluate a new type of multi-cancer early detection test called EnlightenTM. Unlike other recently developed early cancer detection tests that focus on measuring signals released by tumours, the EnlightenTM test measures the host immune response to tumour development.

Who can participate?
Patients diagnosed with or symptomatic of bladder cancer, breast cancer, colorectal cancer, lung cancer, melanoma cancer, oesophageal cancer, ovarian cancer, pancreatic cancer, prostate cancer and renal cancer. Healthy volunteers who are registered to the Southampton CRF Healthy Volunteer register.

What does the study involve?
The study will collect a single 4 mL blood sample from 1000 cancer patients and 350 controls. The plasma sample will be analysed using the new developmental test, in the context of the deidentified clinical data.

What are the possible benefits and risks of participating?
This is an observational study and participants will not receive any information on their sample's test results, however, this study will help researchers better understand the EnlightenTM test and may help aid future implementations for the early detection of cancer. There is a minor risk of patient injury (e.g., bruising) during the blood draw.

Where is the study run from?
University of Southampton Clinical Trials Unit (SCTU) (UK)

When is the study starting and how long is it expected to run for?
August 2024 to July 2026

Who is funding the study?
This trial is primarily funded by the National Institute for Health and Care Research (NIHR) in partnership with the Office of Life Sciences (OLS). The study has additional financial support from Cancer Research UK core funding at the Southampton Clinical Trials Unit and it is also supported by the Southampton Experimental Cancer Medicine Centre.

Who is the main contact?
Hannah Warming, modernised@soton.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-new-blood-test-to-find-cancer-early-modernised

Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
338326

Central Portfolio Management System (CPMS)
60138

Study information

Scientific Title
Cost-effective multi-cancer early detection by measuring patient plasma amino acid cross sections with the Enlighten test

Acronym
MODERNISED

Study objectives
Improving early diagnosis is a priority for cancer researchers and the NHS. Currently, there are four screening programmes in the UK, for bowel, breast, cervical and lung cancer and screening is only for one cancer at a time. The MODERNISED trial will evaluate whether the ENLIGHTEN test, developed by biotech company Proteotype Diagnostics, can predict if a patient has one of 10 cancer types using a blood sample. Unlike most current research into multi-cancer blood tests focussed on detecting abnormal DNA that has been released into the bloodstream, ENLIGHTEN looks at levels of certain proteins which are released by the body's immune system in response to the cancer. The trial will recruit 1000 cancer patients as well as 350 control samples from symptomatic and healthy volunteers. The trial will open at 5 centres in the south of England.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/12/2024, West Midlands – Edgbaston (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)207 104 8155; edgbaston.rec@hra.nhs.uk), ref: 24/WM/0234

Study design
Prospective observational case-control multicentre study with longitudinal follow-up for controls to monitor for cancer diagnosis

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Bladder cancer, breast cancer, colorectal cancer, lung cancer, melanoma cancer, oesophageal cancer, ovarian cancer, pancreatic cancer, prostate cancer and renal cancer

Interventions
This is a prospective, observational, case-control study for the collection of blood for the training and evaluation of the EnlightenTM Multi-Cancer Early Detection test. The test is

comprised of two parts: Part 1 is the Enlighten assay which quantifies amino acid cross-sections from neat blood plasma and Part 2 is the Enlighten algorithm, machine machine-learning process that analyses the assay results to predict a patient's cancer status, cancer tissue of origin and cancer stage.

Blood samples will be collected from 1000 patients recently diagnosed with bladder cancer, breast cancer, colorectal cancer, lung cancer, melanoma cancer, oesophageal cancer, ovarian cancer, pancreatic cancer, prostate cancer and renal cancer. These patients will be identified through the participating site's oncology clinics, and blood will be taken before treatment. Samples will also be collected from 250 symptomatic cancer-free controls, identified through urgent cancer referral pathways and 100 asymptomatic cancer-free controls identified through the University Hospital Southampton NHS Foundation Trust's Healthy Volunteer Register.

Clinical and demographic data will be collected during the patient's blood collection appointment, along with an additional follow-up data collection time point after 3 months. This follow-up data collection time point is used to confirm the patient's cancer status and staging.

The patient's blood sample and clinical data will be used to develop and evaluate the Enlighten algorithm. Patients will be randomised into algorithm development and held-out sets in a ratio of 3:1, balanced by cancer site, to ensure that there is a balance between how the model is being developed and evaluated.

Intervention Type
Other

Primary outcome(s)
Cancer status (presence versus absence of cancer) measured by a cancer diagnosis being present in routine NHS diagnostic records by the end of follow-up

Key secondary outcome(s))
1. Tissue of Origin (1 of 10 solid tumour cancers) measured using the stated Tissue of Origin for the first cancer diagnosis present in routine NHS diagnostic records by the end of follow-up.
2. Cancer stage (stage I/II/III/IV) measured using the stated cancer stage for the first cancer diagnosis present in routine NHS diagnostic records by the end of follow-up.

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. Age 18 years or older
2. Able to provide a written informed consent
3. Willing to provide 4 mL blood sample at the time of enrolment

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
All Participants:
1. Pregnancy (by self-report of pregnancy status), or pregnancy within the last 12 months
2. Current febrile illness
3. Infection requiring hospitalisation within 30 days prior to blood draw
4. Acute exacerbation or flare of an inflammatory condition requiring escalation in medical therapy within 14 days prior to blood draw.
5. Undergone a surgical procedure (including diagnostic biopsy) within 30 days prior to blood draw
6. Undergone a blood transfusion within 30 days prior to blood draw
7. Recipient of organ transplant or prior non-autologous (allogeneic) bone marrow or stem cell transplant
8. Poor health status or unfit to tolerate blood draw

Confirmed Cancer Cohort:
9. Currently receiving, or ever received, any of the following therapies to treat their current cancer: surgical management of the cancer beyond that required to establish the cancer diagnosis; local, regional or systemic chemotherapy including chemoembolization; targeted therapy, immunotherapy including cancer vaccines; hormone therapy; or radiation therapy
10. Known prior diagnosis of cancer, per guidance in protocol, separate from the confirmed or suspected cancer diagnosis associated with study enrolment.
Exception: subjects with history of non-melanoma skin cancer (e.g., BCC or SCC) that has been effectively and exclusively managed by local or focal therapies such as surgical resection, radiation therapy, cryotherapy or topical therapy, are eligible to enrol.
11. Cancer recurrence
12. Synchronous malignancies

Symptomatic and Asymptomatic Cancer-Free Cohort:
13. Known current or prior diagnosis of cancer, per guidance in protocol.
Exception: subjects with history of non-melanoma skin cancer (e.g., BCC or SCC) that has been effectively and exclusively managed by local or focal therapies such as surgical resection, radiation therapy, cryotherapy or topical therapy, are eligible to enrol.
14. Oral or IV corticosteroid use in past 14 days prior to blood draw

Date of first enrolment
23/01/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Portsmouth Hospitals University National Health Service Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
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England
SO16 6YD

Study participating centre
University Hospitals Dorset NHS Foundation Trust
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Study participating centre
Dorset County Hospital NHS Foundation Trust
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DT1 2JY

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

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
The datasets generated during and/or analysed during the current study will be available upon request from the Southampton Clinical Trials Unit Data Sharing Release Committee (sctu@soton.ac.uk).

SCTU is committed to the responsible sharing of clinical study data and samples with the wider research community. Data access is administered through the SCTU Data Release Committee, who will consider requests once the final analysis has been published.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/11/2025	18/11/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes