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Development of liquid biopsy in NHS Tayside: a genetic blood test for patients with pancreatic and colorectal cancer

Submission date
24/01/2025

Recruitment status
Recruiting

Registration date
28/01/2025

Overall study status
Ongoing

Last Edited
28/01/2025

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
At the moment, for both colorectal and pancreatic cancer, clinical decisions are based mainly on two modalities: radiology scans and blood biomarkers (tumour markers), the latter being specific for different types of cancer (CEA for colorectal and CA19-9 for pancreatic cancer, respectively). What we see on scans and how high or not the tumour markers are, dictate the appropriate treatment path for each patient, which usually includes a combination of surgery and/or chemotherapy-radiotherapy. However, since cancer harbours different types of mutations, often patients do not respond to treatment as expected and there are significant delays until this is reflected either on radiology images or on tumour marker levels. Apparently, there is an ongoing delay in optimising patients' treatment, limited by the existing diagnostic modalities. Therefore, the key to improving patient care and outcomes is to open a door and gain insight into tumour biology.
Circulating tumour DNA (ctDNA) is a form of cell-free DNA (genetic material) that originates from tumour cells and is found in the bloodstream. Liquid biopsy, a method that involves the analysis of ctDNA, offers a minimally invasive alternative to traditional tissue biopsies. This technique allows for the detection and monitoring of cancer by analysing blood samples. This is a study on ctDNA in patients with a new diagnosis of pancreatic and colorectal cancer.

Who can participate?
All adults in NHS Tayside with the above new diagnosis

What does the study involve?
The researchers will monitor the ctDNA levels in the participants' bloodstream during their treatment and over the surveillance period with recurring peripheral blood samples.

What are the possible benefits and risks of participating?
The main benefits of the study will be to assess this biomarker as an adjunct to identify disease progression or recurrence more easily. There are no associated risks for the participants, however, any results will not be communicated to them until the end of the study and they will not affect the decision-making process regarding their treatment.

Where is the study run from?
Ninewells Hospital in Dundee, Scotland within NHS Tayside (UK)

When is the study starting and how long is it expected to run for?
April 2024 to October 2028

Who is funding the study?
NHS Tayside Charitable Foundation (UK)

Who is the main contact?
Mr Georgios Gemenetzis, Georgios.gemenetzis2@nhs.scot

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
120879

Study information

Scientific Title

The Tayside Cancer Network (TAY.CA.N) Initiative: Utilisation of circulating tumour DNA (ctDNA) as a clinical biomarker for early detection of disease progression and recurrence in patients with pancreatic and colorectal cancer

Acronym
TAYCAN

Study objectives
The primary hypothesis of this proposal suggests that the presence and ctDNA in the peripheral circulation of patients with pancreatic and colorectal cancer fluctuates according to tumour burden and therefore is directly correlated with presence of disease. As a result it can be utilised as a biomarker for early detection of disease recurrence or progression.

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted 27/01/2025, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design
Single-centre longitudinal observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention, Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Disease progression and recurrence in pancreatic and colorectal cancer

Interventions
Eligible patients will be recruited in the study and will undergo further genomic testing of the acquired biopsies for diagnostic purposes to determine the genetic profile of the primary tumours and recurring peripheral venous blood sampling to assess the presence and burden of said mutations in the bloodstream.

Intervention Type

Other

Primary outcome measure
ctDNA levels for cancer-specific mutations measured with next-generation sequencing (NGS) at baseline and every 2 months between treatment modalities, until proof of disease recurrence or patient death/loss to follow up

Secondary outcome measures
Measurement in days of the lead changes in ctDNA levels compared to evidence of disease recurrence on traditional biomarkers (CA19-9, CEA) and on imaging (CT, MRI)

Overall study start date
01/04/2024

Completion date
01/10/2028

Eligibility

Key inclusion criteria
1. All patients with a new diagnosis of pancreatic or colorectal cancer between ages 18-80 years
2. A cohort of healthy individuals (no previous cancer diagnosis) will be the control group and will need to provide a sample of peripheral blood samples to prove the lack of mutant genetic material in their bloodstream

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. For participants with a pancreatic or colorectal cancer diagnosis: past medical history of a different primary malignancy
2. For healthy participants: previous diagnosis of cancer

Date of first enrolment
01/05/2025

Date of final enrolment
01/05/2027

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Tayside
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
NHS Tayside

Sponsor details
Research & Development Office
Tayside Medical Science Centre (TASC)
Residency Block Level 3
George Pirie Way
Ninewells Hospital
Dundee
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United Kingdom
DD1 9SY
+44 (0)1382 383297
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Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/index.htm

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Charity

Funder Name
NHS Tayside Charitable Foundation

Results and Publications

Publication and dissemination plan
The results of the study will be communicated to NHS Tayside with a goal to establish ctDNA as a clinical diagnostic test in patients with pancreatic and colorectal cancer. Further planned publication in a peer-reviewed journal and presentation in national and international conferences is intended.

Intention to publish date
01/01/2029

Individual participant data (IPD) sharing plan
The datasets generated and analysed will be available on request from Georgios Gemenetzis (Georgios.gemenetzis2@nhs.scot)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			28/01/2025	No	No