

Analysis of liquid biopsies to improve diagnosis and follow-up in cancer and other conditions

Submission date 08/02/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/06/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/06/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Liquid biopsies (LBs) are minimally invasive samples of body fluids that contain tiny amounts of circulating tumour-derived (ct) DNA, RNA and proteins. Thanks to new, ultrasensitive techniques, LBs have emerged as a potential cancer biomarker. It has been shown that analysis of ctDNA from liquid biopsies using broad screening methods, including whole-genome or targeted gene panel sequencing, and sensitive methods that target specific genetic aberrations is possible. Further techniques are being developed for analysing all the components (including RNA and proteins) for multi-omic analysis of LBs (m-LBs), to increase sensitivity and precision. Together with the doctors involved in cancer care, the research team have identified three core clinical questions which will be used to test LBs: 1. Can LBs provide a molecular diagnosis when tissue biopsies are not available (such as some brain tumours)?; 2. Are LBs as good (or better) as current clinical tests for providing information on prognosis and risk for developing metastatic disease?; and, 3. Can LBs be successfully used to monitor therapy response and detect early relapse?

Who can participate?

Patients with cancer, risk of cancer and other somatic conditions

What does the study involve?

LBs (blood, cerebrospinal fluid when available, urine) will be collected from study participants. The analyses are performed retrospectively and will not be used in the treatment or follow-up of the participants.

What are the possible benefits and risks of participating?

There are no direct benefits to participating in this study. The aim is to improve the diagnosis and follow-up of future patients with the same condition. The risks are minor and include minor complications from taking the samples (done in conjunction with clinical sampling) and the small risk (or benefit depending on how you look at it) that a germline predisposition can be identified that would enable us to offer you more information on possible cancer risks and to refer you to an individualised risk reduction program. The samples are usually collected when other samples are collected clinically which entails minimal risks.

Where is the study run from?
Karolinska University Hospital, Sweden

When is the study starting and how long is it expected to run for?
January 2015 to December 2040

Who is funding the study?
1. The Childhood Cancer Foundation
2. The Cancer Foundation
3. Stockholm County Council

Who is the main contact?
Dr Emma Tham, emma.tham@ki.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Emma Tham

ORCID ID
<https://orcid.org/0000-0001-6079-164X>

Contact details
Clinical Genetics and Genomics
Karolinska University Hospital
Stockholm
Sweden
171 76
+46-12370000
emma.tham@ki.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Multi-omics analyses of liquid biopsies

Acronym
Multi-Liq

Study objectives

Liquid biopsies can be used as a complement to standard-of-care methods to provide a molecular diagnosis in patients where no tumour biopsy is available and to refine risk stratification and monitoring during treatment and follow-up of cancer patients

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 12/09/2016, Regional Ethics Review Board (Tomtebodavägen 18, Stockholm, 171 77, Sweden; +46 08-52487000; kansli@stockholm.epn.se), ref: 2016/2-31/1

2. approved 19/01/2025, The Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46-10-475 08 00; registrator@etikprovning.se), ref: 2024-08384-02

Study design

Prospective multi-centre retrospective analysis. Longitudinal with comparison to standard of care performed in parallel.

Primary study design

Observational

Study type(s)

Diagnostic, Screening

Health condition(s) or problem(s) studied

Cancer, risk of cancer and other somatic conditions

Interventions

The collection and analysis of liquid biopsies using various methods, mostly based on cfDNA, but also with multi-omics approaches. Comparison to diagnosis and follow-up performed within routine clinical care to evaluate the added utility of liquid biopsies.

Intervention Type

Not Specified

Primary outcome(s)

Additional diagnostic or prognostic information provided by liquid biopsies measured using massive parallel sequencing, methylation analysis or targeted digital PCR at diagnosis

Key secondary outcome(s)

Prognostic information and correlation to survival from liquid biopsies measured using massive parallel sequencing, epigenetic analysis, targeted digital PCR and/or proteomics at diagnosis, during or after treatment or during follow-up

Completion date

31/12/2040

Eligibility

Key inclusion criteria

1. Patients with cancer of a type included in the study
2. Individuals with a predisposition for cancer
3. Individuals with other somatic conditions not classified as cancer
4. Not able to give informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

All

Lower age limit

0 days

Upper age limit

100 years

Sex

All

Key exclusion criteria

Not meeting the participant exclusion criteria

Date of first enrolment

15/11/2016

Date of final enrolment

31/12/2035

Locations**Countries of recruitment**

Sweden

Study participating centre

Karolinska University Hospital

Eugeniavägen 3

Stockholm

Sweden

17176

Study participating centre

Akademiska Sjukhuset
Akademiska Sjukhuset
Uppsala
Sweden
751 85

Sponsor information

Organisation

Karolinska University Hospital

ROR

<https://ror.org/00m8d6786>

Funder(s)

Funder type

Research organisation

Funder Name

Barncancerfonden

Alternative Name(s)

Swedish Childhood Cancer Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

Cancerfonden

Alternative Name(s)

Swedish Cancer Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Sweden

Funder Name

Stockholms Läns Landsting

Alternative Name(s)

Stockholm County Council

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

Japanese Swedish Foundation

Funder Name

Karolinska Institutets Funds

Results and Publications

Individual participant data (IPD) sharing plan

All participants receive written and oral information on the study and provide written informed consent. The results from the liquid biopsy analyses and the clinical data will be stored in a non-publicly available study repository (only available to the researchers involved in the project) and relevant results will be published in peer-reviewed journals

IPD sharing plan summary

Stored in non-publicly available repository