ISRCTN35928837 https://doi.org/10.1186/ISRCTN35928837

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

Submission date 08/02/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 06/06/2025	**Overall study status** Ongoing	
Last Edited 06/06/2025	**Condition category** Cancer	

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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Longitudinal study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Diagnostic, 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
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 measure
Additional diagnostic or prognostic information provided by liquid biopsies measured using massive parallel sequencing, methylation analysis or targeted digital PCR at diagnosis

Secondary outcome measures
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

Overall study start date
01/01/2015

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

Age group
All

Lower age limit
0 Days

Upper age limit
100 Years

Sex
Both

Target number of participants
10000

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

Sponsor details
Eugeniavägen 3, Solna
Stockholm
Sweden
SE-171 76
+46 8 123 70 000
kontakt@regionstockholm.se

Sponsor type
Hospital/treatment centre

Website
https://www.karolinskahospital.com

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

Publication and dissemination plan
Results will be published in scientific peer-reviewed journals

Intention to publish date
31/12/2036

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-publically 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