ISRCTN12948913 https://doi.org/10.1186/ISRCTN12948913

Biolymph - a study of the causes and biology of lymphoma

Submission date
23/03/2021

Recruitment status
No longer recruiting

Registration date
30/03/2021

Overall study status
Ongoing

Last Edited
18/09/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Malignant lymphomas are a diverse group of diseases where lymphatic tissue undergoes a malignant transformation to cancer cells. About 2000 new cases of malignant lymphomas are diagnosed each year in Sweden. There's increasing awareness that lymphomas are caused by multiple genetic changes. Thanks to the rapid development of methods to genetically analyse tumours researchers now have the ability to genetically characterise the DNA in tumours of all newly diagnosed lymphoma patients at Karolinska University Hospital. By analysing tumour DNA, they aim to increase understanding of how lymphomas arise and how to best predict and treat lymphomas.
In cancer some cells break and tumour DNA enters the blood circulation as cell-free DNA. Tumour-specific genetic variants may be identified in these DNA fragments. This method (also known as liquid biopsies) has recently emerged as a very promising way to assess genetic changes in several cancer forms. Thus, this study also aims to assess the use of liquid biopsies in lymphoma and find out whether liquid biopsies can provide diagnostic information, as well as information regarding response to treatment and risk of relapse.

Who can participate?
All adult patients with a newly diagnosed lymphoma at the Karolinska University Hospital, Stockholm.

What does the study involve?
The study involves the collection of tumour material (already collected in routine clinical care), extra blood samples at diagnosis and during and after treatment, and filling in questionnaires on quality of life, fatigue and neuropathy at diagnosis and at 1,2 and 5 years after diagnosis.

What are the possible benefits and risks of participating?
Primarily, future lymphoma patients are projected to benefit from the current study, but is possible that some individual patients will benefit from knowing the genetic status of their lymphoma for example for treatment choice in a relapse setting. The risks of involvement are projected to be small as all samples are taken in planned routine clinical care, and only small amounts of additional blood samples are collected. In addition, participants will need to spend some time filling in questionnaires at diagnosis and 1, 2 and 5 years after diagnosis.

Where is the study run from?
Karolinska Institutet and Karolinska University Hospital (Stockholm)

When is the study starting and how long is it expected to run for?
February 2012 to February 2030

Who is funding the study?
The study is funded by grants from the Swedish Cancer Society, Stockholm County Council, Karolinska University Hospital, King V Jubilee Fund and Genome Medicine Sweden

Who is the main contact?
Karin Ekström Smedby
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Prospective study of biology, aetiology and survival in lymphoma (BioLymph)

Acronym

Biolymph

Study objectives
The general aim of this project is to further investigate the clinical significance of different genetic alterations in lymphomas and try to identify the genetic lesions that actually drive tumour progression, influence the response to different treatment alternatives, and affect survival. Further, the project aims to evaluate the potential clinical value of liquid biopsies as a DNA source for tumour characterisation, and marker of response and relapse.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/02/2018, addition approved 22/11/2020, regional ethics board Stockholm (regionala etikprövningsnämnden Stockholm, FE 289, Karolinska Institutet, 171 77, Stockholm, Sweden; +468 (0)524 870 00; kansli@epn.stockholm.se), ref: 2017/2538-31, 2020-05978

Study design
Prospective single-centre observational study with population-based inclusion

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Malignant lymphoma

Interventions
All newly diagnosed lymphoma patients at Karolinska University Hospital are asked to participate. Participation involves the collection of tumour material for genetic analysis (using a lymphoma panel [TWIST]), consisting of approximately 250 genes known to be frequently mutated in lymphomas. Blood samples for normal DNA will be obtained at diagnosis. Blood samples for liquid biopsies will be obtained at diagnosis, during and after treatment to assess cell-free tumour DNA. Further, participating patients will fill in questionnaires on quality of life, fatigue and neuropathy at diagnosis and after 1, 2 and 5 years.

Intervention Type
Other

Primary outcome measure

Number and type of genetic driver mutations potentially relevant for diagnosis, prognosis and treatment prediction, assessed by next-generation sequencing (NGS) for each tumour case at diagnosis.

Secondary outcome measures
1. Progression-free survival, assessed using data from medical records, the Swedish lymphoma register and Swedish cause-of-death register from the date of study inclusion to relapse, death or end of follow-up
2. Overall survival assessed using the Swedish cause-of-death register from the date of study inclusion to death or end of follow-up
3. Level of cell-free tumour DNA measured quantitatively using haploid genome equivalents per ml of plasma at diagnosis, after the first treatment, at interim analysis, end-of-treatment and once yearly
4. Quality of life assessed using the EORTC QLQ-30 questionnaire at diagnosis and at 1, 2 and 5 years after diagnosis

Overall study start date
01/02/2012

Completion date
01/02/2030

Eligibility

Key inclusion criteria
Newly diagnosed adult (aged 18 years or above) lymphoma patients

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/02/2019

Date of final enrolment
01/02/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska University Hospital
Department of Haematology
Solna
Stockholm
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17174

Sponsor information

Organisation
Karolinska University Hospital

Sponsor details
Eugeniavägen 3
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Sponsor type
Hospital/treatment centre

Website
http://www.karolinska.se/en

ROR
https://ror.org/00m8d6786

Funder(s)

Funder type
Charity

Funder Name

Swedish Cancer Foundation

Alternative Name(s)

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
Karolinska University Hospital

Funder Name
King V Jubilee Fund

Funder Name
Genome Medicine Sweden

Results and Publications

Publication and dissemination plan

Current publication and dissemination plan as of 18/09/2024:
Planned publications in high-impact journals. The researchers have started publishing articles based on data from the study, with many subsequent publications planned.

Previous publication and dissemination plan:
Planned publications in high-impact journals. The researchers expect to publish the first reports during 2025, and a study protocol during 2021. The current study protocols and statistical plans are currently only available in Swedish.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
All data will not be available on request (for example personal data will not be available to preserve anonymity) due to, for example, GDPR limitations and ethical consent that states that data needs to be anonymised and aggregated for sharing. The researchers will share aggregated data upon request given that necessary agreements can be obtained and national and institutional legal requirements are met. The investigator to contact for this is Prof. Karin Ekström Smedby (karin.ekstrom.smedby@ki.se).

IPD sharing plan summary
Available on request, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/04/2021	No	Yes
Other publications	proof-of-concept study	02/06/2023	06/11/2023	Yes	No
Protocol article	feasibility and first results	06/07/2023	06/11/2023	Yes	No