Clinical aspects and molecular mechanisms in large granular lymphocyte (LGL) leukemia - IDeAL study

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Overall objective of this IDeAL study is to unravel the biological heterogeneity of LGL leukemia and to correlate this with the clinical features. More specific objectives are: 1. Build a LGL leukemia registry (clinical features and lab data).2. Set...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON55452

Source
ToetsingOnline

Brief title
Research into clinical aspects and molecular mechanisms in LGL leukemia

Condition

- Leukaemias

Synonym
blood cancer, Large granular lymphocyte leukemia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Hoffmann-La Roche,Unrestricted research grant;Hoffman-La Roche (zie ook G2a)

Intervention

Keyword: LGL leukemia

Outcome measures

Primary outcome

Observational study without formal endpoints. At the end of this study, more

insights will be gained about the following parameters:

• fenotypical features

• clonal TCR repertoire at DNA / RNA and possibly functional level

• (epi)genetic and transcriptional patterns

• (auto)antibodies and cytokines

Secondary outcome

NA

Study description

Background summary

LGL leukemia is a rare form of leukemia and is heterogeneous in course and clinical presentation. The etiology and pathophysiology is largely unknown; therefore better understanding of the mechanisms that cause survival of the LGL cells is necessary. Therefore we have the intention in this study to start a LGL registry to get more insight in the clinical characteristics and biological mechanisms of LGL leukemia, which will eventually lead to newer and better therapeutic options.

Study objective

Overall objective of this IDeAL study is to unravel the biological heterogeneity of LGL leukemia and to correlate this with the clinical features.
More specific objectives are:
1. Build a LGL leukemia registry (clinical features and lab data).
2. Set up LGL leukemia biobank (blood cells, DNA / RNA, plasma).
3. Determine LGL leukemia fenotype compared to normal T-/NK- cells (and

subtypes) in healthy elderly.
4. Determine the clonal TCR repertoire of T-LGL leukemia compared to the TCR repertoire in healthy elderly and evaluate the significance of TCR signaling.
5. Determination of (epi)genetic and transcriptional changes that discriminate LGL leukemic cells from their normal counterparts.
6. Evaluation of biomarkers in cells and/of plasma in LGL leukemia.

Study design

Prospective observational study

Study burden and risks

There is a minimal extent of burden for the patients and risks are negligible. With this study we aim to get insight about the biological mechanisms of LGL leukemia, which will eventually lead to newer and better therapeutic options.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Wytemaweg 80
Rotterdam 3015 CN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with LGL leukemia / lymphoproliferation

Exclusion criteria

No consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-07-2019
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	17-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-05-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65165.078.18