Molecular Analysis of Cutaneous T-cell Lymphoma Cells Isolated From Skin

Published: 20-09-2024
Last updated: 27-12-2024

To characterize the genomic alterations and investigate the functional consequences of these alterations in isolated tumor cells from MF and CD30+ LPD.

Ethical review	Approved WMO
Status	Pending
Health condition type	Lymphomas non-Hodgkin's T-cell
Study type	Observational invasive

Summary

ID

NL-OMON57121

Source
ToetsingOnline

Brief title
MACTIS

Condition

- Lymphomas non-Hodgkin's T-cell
- Lymphomas non-Hodgkin's T-cell

Synonym
Cutaneous lymphoma, skin lymphoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anaplastic Lymphoma, Cutaneous Lymphoma, Mycosis Fungoides, Sezary Syndrome

Outcome measures

Primary outcome

The main study parameters are the prevalence of 1. genetic alterations

(mutations, copy number alterations, translocations and DNA methylation) and

2.short term cultures as well as mouse models will be used to evaluate

cytotoxic effect of selected drugs, including (but not limited to) anti CD30

antibodies, and inhibitors of JAK/STAT signalling.

Secondary outcome

Development of CTCL cell lines.

Study description

Background summary

Cutaneous T-cell lymphoma (CTCL) are a rare and heterogeneous group of lymphomas that originate in the skin. Around 50% of CTCL are patients with mycosis fungoides (MF) which is the most common type of cutaneous lymphoma. Sezary syndrome (SS) is a rare type of CTCL in which tumor cells are found in skin, lymph nodes and blood. Patients with SS present with a pruritic erythrodermia, lymphadenopathy and have a poor prognosis. The second most common type of CTCL is the spectrum of CD30+ lymphoproliferative diseases (LPD) that includes on the one end cases of CD30+ primary cutaneous anaplastic large cell lymphoma (pcALCL) and on the other end lymphomatoid papulosis (LyP) as well as intermediate cases. At present CTCL are incurable with the exception of allogenic stem cell transplantation which has considerable treatment related morbidity and mortality. Insight in the dominant oncogenetic pathways driving CTCL is still limited and further insight in the molecular alterations underlying the development and progression MF, SS and CD30+ LPD might provide new therapeutic targets that are urgently needed in particular in patients with advanced disease.

Study objective

To characterize the genomic alterations and investigate the functional consequences of these alterations in isolated tumor cells from MF and CD30+ LPD.

Study design

Prospective, observational study

Study burden and risks

Two four mm skin biopsies will be obtained from lesional skin at a routine visits to the clinic. There are no high risks to be expected with this approach. There is only a (very low) risk (<5%) of a wound infection after biopsy.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 1333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 1333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age between 18-90 years
Established diagnosis of MF, SS, LyP, or pc ALCL
Skin lesions
Not receiving therapy

Exclusion criteria

Ongoing infection
Patients younger than 18 years of age

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-09-2023
Enrollment:	55
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-09-2024

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-11-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL84066.058.23