Towards personalized medicine for refractory/relapsed Follicular Lymphoma patients: the Cantera/Lupiae registry

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28193

Source
Nationaal Trial Register

Brief title
LUPIAE

Health condition

follicular lymphoma

Sponsors and support

Primary sponsor: EHA Lymphoma group
Source(s) of monetary or material Support: Associazione Angela Serra per la Ricerca sul Cancro

Intervention

Outcome measures

Primary outcome

Rate of Progression of disease within 24 months from start of second line treatment (second POD24)

Secondary outcome

Overall Survival (OS), Progression-free survival after second line therapy (second PFS), Complete response rate at 30 months (CR30) from start of second line treatment (second CR30)

Study description

Background summary

The optimal treatment strategy in patients with early progressive disease is not well known. In recent years, novel insights into the biology of FL, and especially the role of the microenvironment, have resulted in the development of multiple novel treatment modalities. These new agents may ultimately improve the outlook for patients with FL with an unfavorable course, but for the development of the optimal therapeutic strategy, knowledge on the clinical and biological determinants of early refractory FL is needed.

Study objective

NA

Study design

NA

Contacts

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Eligibility criteria

Inclusion criteria

Patients with initial diagnosis of follicular lymphoma, refractory/relapsed/transformed after first line therapy, All stages at the time of relapse, Histological grade 1-3a at the time of initial diagnosis, Age over 18 years, Availability of clinical data, including baseline information, comorbidities, data on disease localization, laboratory parameters at staging, features of treatment adopted and assurance of follow-up updating as requested, Diagnostic material available for review, Written informed consent.

Exclusion criteria

Age < 18 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-07-2019
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

It is responsibility of the Study Coordinators to publish the study results after the completion of the study. It will be ensured that the data from one center are not published before the publication of the whole study. All publications regarding the results of the study will be marked with the sentence “on behalf of the EHA-LyG/Cantera-Lupiae study group". Participating centers and sites will be mentioned according to their overall contribution to the study, while all members of the study group will be included as authors of the manuscripts for their active contribution on the study design and procedures. No publication can occur without agreement of the study sponsor. Study results will be submitted for publication in peer-reviewed journals and for presentation at appropriate scientific meetings and conferences.

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL7865
Other	Medical Ethics Review Committee of the Academic Medical Center : W18_431

Study results