

NEW ERIC/HARMONY PROJECT:

Other malignancies in the history of CLL

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OTHER MALIGNANCIES IN CLL

BACKGROUND

- **Other malignancies occurring in patients with chronic lymphocytic leukaemia (CLL) are a well-known, but insufficiently investigated area, highlighting the need for further investigation.**

TYPE OF THE STUDY

- **Multicentric retrospective analysis on real-world evidence (RWE) patient data**

MAIN OBJECTIVES OF THE STUDY

The purpose of this project is to leverage the understanding of other malignancies in patients with CLL, particularly regarding potential links to immunochemotherapy and/or novel therapies as well as associations with relevant clinicobiological factors.

Primary objective

To describe the spectrum of other malignancies occurring in patients diagnosed with CLL and treated/untreated

To identify potential risk factors for other malignancies in CLL

Secondary objectives

To describe demographic and epidemiological data of patients with CLL and other malignancies

To evaluate potential links with/associations to various clinicobiological features of the patients, the administered therapy for CLL and outcome

PROJECT LEADERS AND COORDINATORS



PROJECT LEADERS

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} HARMONY KOLs (key opinion leaders)

PROJECT COORDINATORS

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SAMPLE SET

Inclusion criteria

Data from consecutive set of patients with CLL (diagnosis between years 2000 and 2016)

Clinical and laboratory data available

Data sources

Chart review or CLL registries

REQUESTED VARIABLES

General personal information

Diagnosis CLL/SLL

Demographics (age, gender, ethnicity, occupation)

Comorbidities

CLL data (date of diagnosis, treatment, treatment response, death, reason of death)

Other malignancy (type, date of diagnosis, therapy, response)

CLL-related parameters (staging, FISH, *IGHV*, karyotype, *TP53*)

DATA PROCESSING

Collection of the data after the definition of the mandatory fields

Cleaning of the data (check for selection biases, such as country)

Descriptive analysis

Univariate/Multivariate analysis

Time to event analysis

Visualization

ENDPOINTS

PRIMARY ENDPOINTS

Descriptive statistics of other malignancies in CLL patients

Univariate and multivariate analysis of clinical, biological, demographic factors for other malignancies occurrence

SECONDARY ENDPOINTS

Patient characteristics (gender, age, CLL prognostic factors)

CLL therapy duration and sequence of therapies in CLL patients with other malignancies

Overall survival of CLL with other malignancies

DATA PROVIDERS AND ANALYTIC TEAM

Data providers

ERIC members (potential new Associated Members)

HARMONY Partners and Associated Members from the first CLL HARMONY project

Analytics team

ERIC data center

In collaboration with HARMONY Data Platform if analytical people are available

TIMELINE OF THE PROJECT

Q1/2020 - ERIC: Proposal writing, ERIC board approval and recruitment survey

Q1/2020 - Survey sent to ERIC members

Q2/2020 – 84 sites interested in participating (more than 15,000 patients), table for data collection sent out

Q3/2020 - Collection of data (deadline August 31, 2020)

Q4/2020 - Curation of data

Q1/2021 - Data analysis

Q1/2021 - Submission of congress abstracts (EHA 2021)

Q2/2021 - Final manuscript

THANK YOU FOR YOUR ATTENTION

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