AGMT_ALL REGISTRY

Registry and Biobank for the collection of clinical data and biomaterial from adult ALL patients

NIS Number: NIS002823

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Protocol Synopsis

Indication: Adult acute lymphoblastic leukemia (ALL)

Planned sample size: 70 patients per year

Design: Retrospective and prospective, observational, multicenter research initiative

Recruitment: First patient in (FPI): Q2 2012

Objective: Data collection regarding diagnosis, therapy and progression of disease for Austian ALL patients older than 18 years

Biobank: Within the ALL registry biomaterial should be collected at diagnosis and once a year for 5 years and at relapse

Study Design

In Austria approximately 70 patients are diagnosed with adult ALL per year and are treated in up to 17 institutes. Obviously there is a need to collect all data possible in order to harmonize diagnosis and treatment and to make optimal therapy available for every Austrian patient. Therefore information on these patients should be prospectively collected, analysed and used for the generation of treatment protocols by a specialized study group.

The Austrian ALL study group has been founded to take over this task. As a first step a registry with a standardized data set including diagnosis, therapy and outcome should be implemented.

This study is a registry and not an interventional clinical study. However, in order to achieve a maximum of data harmonisation it is recommended that patients are treated according to a standardized international protocol endorsed by the EWALL (European Working group for Adult Lymphoblasitc Leukemia).

Associated with the registry a central biobank should be established for the collection of peripheral blood and bone marrow. During the last years the utility of molecular cytogenetics in adult ALL is an emerging topic. Several prognostic markers have been discovered and new targeted drugs are available. The use of molecular diagnosis in disease monitoring, risk stratification and the use of target orientated therapies are increasingly important in patient management of ALL. These diagnosis tools are currently not implemented in Austria. For that reason there are many open questions in adult ALL and the new prospects leave clinicians with uncertainty about how to optimally manage adult patients with ALL. A centralized and standardized diagnosis program is needed to assure quality.

Biobank

Biomaterial should be collected in a biobank to be used in ALL related research projects. As a basis for future research, the collection of biomaterial will help medical scientists to develop targeted therapies and to detect molecular targets for new therapies. A centralized biobank is the appropriate tool to collect these materials under strict ethical and legal regulations.

The collection of biomaterial is not categorically connected to the registry. Material should be obtained during clinical routine.

Within the ALL registry biomaterial should be collected at diagnosis, once a year for five years and at relapse.

Assessments

- Collect informed consent
- Registration of the patient at first diagnosis
- Documentation during therapy at regular intervals every 6 months
- Documentation of response
- Follow up once a year for 5 years
- Documentation of relapse and following therapies

Inclusion Criteria (selected)

- Signed written informed consent
- Male or female ≥ 18
- Acute lymphoblastic leukaemia (all types according to WHO classification 2008)
- Diagnosis of specific NHL subtypes (WHO classification):
  - B-lymphoblastic lymphoma
  - T-lymphoblastic lymphoma
  - Burkitt´s lymphoma
  - Aggressive lymphoma with c-myc translocation
  - Other high risk lymphomas treated with ALL protocols

Due to the non-interventional design of the registry there are no exclusion criteria.

Status (as of March 2019)

Site	Patients
PMU Salzburg / Innere Medizin III	7
AKH MUW / Innere Medizin I - Hämatologie	115
Klinikum Wels Grieskirchen / Innere Medizin IV	17
Ordensklinikum Linz/ Interne I	13
Kepler UK, Med Campus III./ UK Hämatologie	12
Hanusch KH Wien / 3. Medizin	0
LKH Feldkirch / Innere Medizin II - Interne E	3
Kaiser-Franz-Josef Spital Wien / 3. Medizin	13
KH Hietzing / 5. Medizin	0
LKH Hochsteiermark / Dep. Hämato- Onkologie	0
UK Innsbruck / Innere Medizin V	in submission
TOTAL	**180**

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An academic registry
Sponsor: Arbeitsgemeinschaft medikamentöse Tumortherapie gemeinnützige GmbH,
Clinical-Scientific Director: R. Greil