Austrian Registry and Biobank of Peripheral T-cell Lymphomas

Protokoll Nummer: AGMT_PTCL-Reg

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Protocol Synopsis:

Indikation: Peripheral T-cell lymphomas (PTCL)
Design: prospective as well as retrospective, observational, multi-center research initiative.
Objectives: Epidemiology of this rare disease in Austra
Information on type of therapy
Response
Identification of potential prognostic and predictive factors

Inclusion Criteria:

- Diagnosis of peripheral T-cell lymphomas (PTCL) according to WHO classification 2008
- Written informed consent (deceased patients may also be included without written consent)
- Age > 12 years. For inclusion of patients between >12 years and <18 years of age, additional written informed consent has to be obtained by the patient's parent(s) or guardian.

Rationale and Design:

Peripheral T-cell lymphomas (PTCL) comprise a heterogeneous group of hematological neoplasms originating from post-thymic T-cells at different stages of differentiation. Due to several reasons clinical management of PTCL probably represents one of the most challenging tasks in hematologic oncology:

- Patients often present at higher stages and with reduced performance status
- PTCL do not respond well to chemotherapy
- PTCL are rare

The lack of knowledge of the epidemiology and biology of this rare disease and above all, the urgent clinical need for improved therapies for PTCL are the primary motivations for this registry and biobank. The "AGMT_PTCL-registry" should strengthen meaningful research on PTCL in Austria with the ultimate goal of furthering our understanding of this disease in all possible ways and eventually improving patients´ lives.

This registry is a prospective as well as retrospective, observational, multi-center research initiative. Data will be collected from all sites in Austria willing to participate.

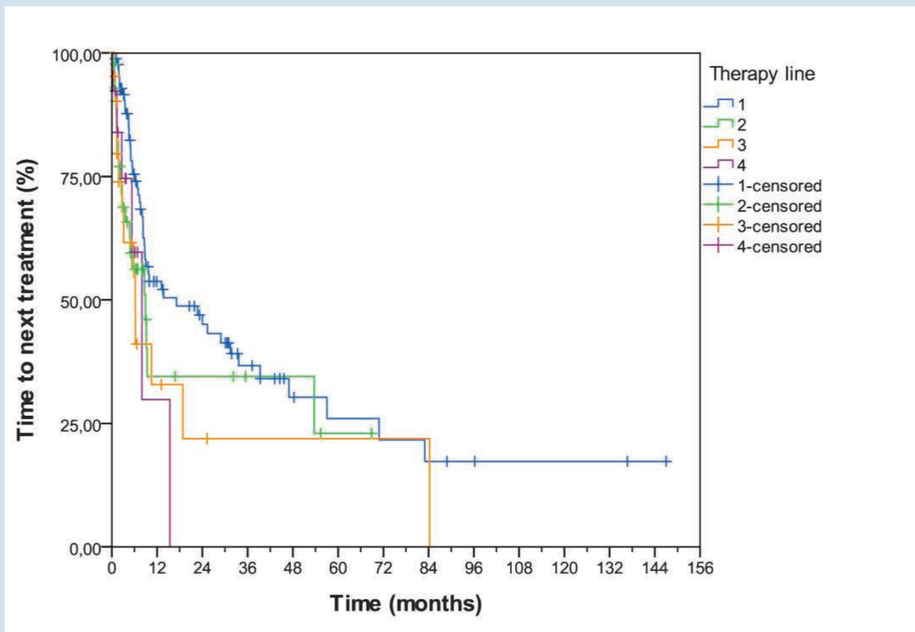
Within the registry biomaterial should be collected in the AGMT biobank. Given the low incidence of PTCL, only the establishment of a substantial biobank can lay the foundations for scientifically meaningful and internationally competitive translational research.

No	*Site*	*Patients*
01	PMU Salzburg / III. Med	76
02	UK Innsbruck / Med. V	1
03	Klinikum Wels Grieskirchen / Med. IV	7
04	LKH Feldkirch / Interne E	10
05	LKH Steyr / Med. II	1
06	Kaiser-Franz-Josef Spital Wien	5
07	Elisabethinen Linz/ I. Interne	6
08	Kepler UK, Med Campus III./ Interne 3	1
09	UK Graz / Innere Med.	0
	TOTAL	**107**

Results:

Epidemiologic data review (before start of first line therapy)	
Median age, years (range, IQR) n=105	62 (19-92, 49-72.5)
Sex	
Men	61 (57%)
Women	46 (43%)
Diagnosis	
Peripheral T-cell lymphoma (PTCL), NOS	35 (34%)
Angioimmunoblastic T-cell lymphoma (AITL)	9 (9%)
Anaplastic large cell lymphoma (ALCL), ALK-positive	8 (8%)
Anaplastic large cell lymphoma (ALCL), ALK-negative	12 (12%)
Other	38 (37%)
Initial disease presentation	
Nodal	76 (77%)
Leukemic	8 (8%)
Cutaneous	12 (12%)
More than one	3 (3%)
Stage	
Stage I, stage II	22 (30%)
Stage III, stage IV	52 (70%)
Extranodal disease presentation n=95	40 (39%)
Bone marrow involved n=80	14 (19%)
ECOG performance status	
0, 1	38 (84%)
2, 3	7 (16%)
Serum LDH, U/L (median, IQR) n=75	261 (191-378)

Induction therapy is actually documented for 92 patients: 41 patients received only 1st line therapy so far, 28 patients had 2 lines of therapy, 23 patients underwent 3 or more therapy lines. The median number of lines per patient was 2 (range 1-10, IQR 1-3). Most common first line induction therapy was CHOP or CHOP-like therapy (62 of 92 patients). In 2nd line treatment with DHAP or DHAP-like therapy regimen was most common (16 of 51 patients) followed by Brentuximab vedotin (7 of 51 patients). Treatment within a clinical trial was performed in only 5 out of 82 patients in the 1st line setting and 2 out of 45 patients in the 2nd line setting.



Median time to next treatment in first line induction therapy was 17.2 months (95% CI 1.854; 32.469). Median overall survival was 31.4 months (95% CI 15.073; 47.722).

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