Registerstudie – Seltene Maligne Tumore der Schilddrüse

AIO-YMO/ENC-0216: Multicenter registry for patients with rare malignant tumors of the thyroid (ThyCa)

AIO-Studie	Eine Studie der Young-Medical-Oncologists (YMO)
Studiennummer/-Code:	AIO-YMO/ENC-0216 - ThyCa
Rekrutierungszeitraum:	retrospektiv 2000 – 2013, prospektiv seit 2014
Weitere Zentren:	sind sehr erwünscht
Letzte Aktualisierung	Oktober 2023

Art der Studie Study Type	Retrospective and prospective registry study
Kontaktadresse/ Kontaktperson:	Prof. Dr. Dr. Matthias Kroiß LMU Klinikum Medizinische Klinik und Poliklinik IV Endokrinologie/Diabetologie Ziemssenstr. 5 80336 München Tel.: 089/4040-52221 Email: matthias.kroiss@med.lmu.de Dr. V. Köhler Medizinische Klinik und Poliklinik IV Endokrinologie/Diabetologie Marchioninistr. 15 81377 München Tel.: 089/4040-73107 Email: Viktoria.koehler@med.uni-muenchen.de Prof. Dr. C. Spitzweg Medizinische Klinik und Poliklinik IV Endokrinologie/Diabetologie Marchioninistr. 15 81377 München Tel.: 089/4040-73012 Email: christine.spitzweg@med.lmu.de Studiensekretariat: J. Putz Tel.: 089/4400-52414 Email: jacqueline.putz@med.lmu.de
Studienziele/ Objectives	Primary objectives: Prospective collection of histopathologic, clinical, clinical chemical and imaging data and biomaterial of newly diagnosed patients with rare malignant tumors of the thyroid (anaplastic thyroid carcinoma, ATC; medullary thyroid carcinoma, MTC; radioiodine refractory differentiated thyroid carcinoma, RR-DTC; poorly differentiated thyroid carcinoma, PDTC) and parathyroid glands (PaTC). The aim is to improve diagnosis and treatment of patients by definition of - Parameters and biomarkers for diagnosis. - Parameters and biomarkers of treatment response and side effects - Parameters for risk stratification.

	- Parameters and biomarkers for follow-up <u>Secondary objectives:</u> Establishment of - cooperative structures for rare malignant tumors of the thyroid. - a clinical cancer registry for rare malignant tumors of the thyroid at the national level with the potential to include centers from European centers. - Structures to facilitate translational research. - Structures to enable future prospective clinical trials. Collaborative evaluation of data collected retrospectively in individual centers.
Zielparameter/ Objectives	overall survival, disease free survival, time to progression, time to recurrence
Patientenzahl Number of patients	not restricted; current recruitment (10/2023): 288 ATC, 699 MTC, 328 RDTC, 39 PaTC
Rekrutierungzeitraum von/bis period of	retrospective: 2000 – 2013 prospective: 2014 – 2023 (planned interim evaluation)
Weitere teilnehmende Zentren erwünscht? More centres?	current centers (10/2023): - LMU Klinikum – Campus Großhadern/Innenstadt - Universitätsklinikum Würzburg - Universitätsklinikum Augsburg - Universitätsklinikum Düsseldorf - Klinikum der Goethe-Universität Frankfurt/Main - Universitätsklinikum Gießen und Marburg – Standort Marburg - Universitätsmedizin Göttingen - Universitätsklinikum Greifswald - Endokrinologische-Nuklearmedizinische Gemeinschaftspraxis Heidelberg - Universitätsklinikum Leipzig - Universitätsklinikum Magdeburg - Klinikum Südstadt Rostock - Universitätsklinikum Schleswig-Holstein – Standort Lübeck - Helios Kliniken Schwerin - Diakonie Klinikum Stuttgart - Universitätsklinikum Freiburg - Universitätsspital Zürich - Kliniken Ostalb – Standort Mutlangen additional centers are invited to participate
Haupt-Einschlusskriterien Key inclusion criteria	Histologically confirmed ATC, MTC, PDTC, PaTC; histologically confirmed differentiated thyroid carcinoma documented to be refractory to radioiodine (RR-DTC).
Haupt-Ausschlusskriterien / Key exlusion criteria	inability to provide informed consent
Therapieschema Scheme of therapy	standard of care; investigational therapies
Tumorevaluierung Criteria for evaluation	standard of care; per protocol for investigational therapies

Rationale	Malignant tumors of the thyroid gland are the most frequent endocrine malignancies in humans. The annual incidence is 1/20.000. More than 90% of thyroid cancers are differentiated thyroid carcinomas (DTC). MTC has its origin from calcitonin producing C-cells of the thyroid. DTC are often detected routinely upon ultrasound examination of the thyroid gland and appear as cold nodules at scintigraphy. In most cases these tumors can be cured by radical surgery and post-operative radioiodine treatment. However, some tumors lose differentiation and become refractory to radioiodine (radioiodine refractory; RR-DTC), others are poorly differentiated at diagnosis (PDTC). ATC mostly appears as a rapidly growing neck mass or through symptoms of tumor invasion into neck structures. Prognosis is very poor even with multimodal treatment. The low incidence of MTC, PDTC, ATC and RDTC has hampered establishment of evidence-based treatment concepts. With the advent of multi-tyrosine kinase inhibitors and other targeted therapies, the therapeutic landscape has changed importantly both in MTC and in RR-DTC. At variance, effective treatment of ATC is still not established.
Statistik statistics (optional)	descriptive statistical methods as appropriate for variable under study; time to event using Kaplan-Meier estimates; comparison between groups using log-rank test; multivariable adjustment using Cox proportional hazard model.