AGMT | ARBEITSGEMEINSCHAFT MEDIKAMENTÖSE TUMORTHERAPIE

PATIENT REGISTRY

Screening for human epidermal growth factor receptor 2 (HER2) positivity in patients with inoperable locally advanced or metastatic gastric or gastro-esophageal junction (GEJ) cancer

Protocol Number: AGMT_GASTRIC 5

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Protocol Synopsis:

Indication: Inoperable locally advanced or metastatic gastric or gastro-esophageal junction (GEJ) cancer

Design: prospective, observational, non interventional, multicenter research initiative

Patients planned: 200 - 300 patients

Recruitment: First patient in (FPI): Q1 2011

Primary objective:

- Rate of HER2 positive locally advanced or metastatic gastric or GEJ cancer

Secondary objectives:

- Comparison of HER2 results from local and central labs
- Safety of chemo-immunotherapy in HER2 positive patients
- PFS and OS after chemo-immunotherapy

Design:

This Registry is a prospective, observational, multi-center research initiative.
In all eligible patients HER2 testing will be performed by means of IHC and in equivocal cases (Score 2+) in addition by ISH. HER2 positive and HER2 negative samples will be sent to a central pathology where a second HER2 testing will be performed. These test results will not influence the treatment of the individual patient, but will be analyzed retrospectively. All HER2 positive patients will receive further therapy at the discretion of the principal investigator. Kind of therapy and duration will be documented.

HER2 Central Testing:

All cases suitable for this registry will be re-tested in a central laboratory.

HER2 IHC will be carried out using the HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody, PATHWAY® (Ventana Medical Systems, Illkirch, France) test kit. Scoring is performed according to Rüschoff et al., using a four tired scoring system ranging from score 0 to score 3+.
Only in cases where a BDISH shows too weak signals or no signals an additional fluorescence ISH (FISH) will be used.
A patient will be determined HER2 positive if IHC is 3+ or if IHC is 2+ and ISH is positive.

First results:

127 samples have already been tested in the local and central laboratory. 20 samples*(15,7%) showed discrepancies between results.

		central lab		*total*
		positiv	*negativ*	
local lab	*positiv*	23	14*	37
	negativ	6*	84	90
total:		27	100	**127**

Inclusion Criteria:

- Locally advanced or metastatic gastric or GEJ carcinoma
- Known HER2 status
- Signed written informed consent

Assessments:

- Collect Informed Consent
- Patient characteristics (year of birth, gender)
- Diagnosis of locally advanced or metastatic gastric or GEJ cancer
- Local and central HER2 testing
- Adverse events
- Therapy
- Response
- PFS, OS

Recruitment:

No	*Zentrum*	*Patienten*
01	KH Zams	15
02	PMU Salzburg / III. Med	57
03	Klinikum Wels Grieskirchen / Med. IV	23
04	UK Innsbruck / Med. V	16
05	KH Ried	5
06	BKH Hall in Tirol	13
07	LKH Steyr / Med. II	8
08	LKH Hohenems	9
09	LKH Hochsteiermark / Hämato-Onkologie	0
10	Kepler UK, Med Campus III./ Interne 3	8
11	LKH Feldkirch / Interne E	29
	TOTAL	**183**

Status as of March 2017

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