

Objectives

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

additional objectives:

- comparison of HER2 results from local and central labs
- safety of chemoimmunotherapy in HER2 positive patients
- progression-free survival time after treatment with chemoimmunotherapy
- overall survival time after treatment with chemoimmunotherapy

Inclusion Criteria

All patients must

- have locally advanced or metastatic gastric or GEJ carcinoma
- be tested for their HER2 status
- be willing to provide informed consent

Due to the non-interventional design there are no specific in- or exclusion criteria.

Design

This Registry is a prospective, observational, multicenter 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 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.

Online CRF

Electronic Case Report Forms will be used for data collection:

<https://ecrf.ibdis.net/>

AGMT

ARBEITSGEMEINSCHAFT
MEDIKAMENTÖSE
TUMORTHERAPIE

AGMT_GASTRIC 5

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

COORDINATING INVESTIGATOR

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An academic registry by AGMT
**Arbeitsgemeinschaft medikamentöse
Tumorthérapie**

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Protocol Version 1.0-Apr-2010

Assessment of HER2 Positivity

Local testing:

For primary HER2 testing of gastric or GEJ carcinoma only standardized and certified IHC test kits or ISH in 2+ cases should be used,.

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 tiered scoring system ranging from score 0 to score 3+. Score 0 or 1+ is mentioned as HER2 negative, score 2+ as HER2 equivocal and score 3+ as HER2 positive.

Only in cases where a BDISH shows too weak signals or no signals an additional fluorescence ISH (FISH) will be used.

HER2 positivity:

A patient will be determined HER2 positive if

IHC is 3+ or if

IHC is 2+ and ISH is positive

Selection of Tissue blocks

Biopsies:

If only biopsies are available, all tissue blocks containing invasive tumor have to be submitted.

For a proper HER2 estimation in a gastric or GEJ carcinoma at least 6-8 biopsies containing invasive tumor should be analyzed.

Resection specimen:

If a resection specimen is available 2 tissue blocks should be selected as follows:

- Intestinal type tumors:
 - blocks containing the invasion front
- Mixed type tumors:
 - blocks containing intestinal differentiated tissue
- Diffuse type tumors:
 - blocks containing the invasion front

Preparation of Tissue Specimens

All tissue samples should be fixed in pH 7.4 buffered 7-10% formalin (i.e. 3-4% formaldehyde solution) and paraffin embedded according to routine histopathology processing. All analyses are carried out on 4-5µm thin tissue sections.

Selection of sample:

- paraffin embedded tumor blocks or
- alternatively 4 tissue sections per block :
 - mounted on coated glass slides used for IHC

Shipment of samples:

- Pack your samples in the provided plastic boxes and affix the completed labels.
- Complete the covering letter and fax it to the number specified on the form to notify AGMT of the shipment.
- The samples are packed in the provided envelope and are—together with the covering letter—sent to the central lab by using the provided boxes (freigestellte medizinische Probe).

Shipping will be done at ambient temperature.

If paraffin blocks are submitted, these will be resubmitted to the source. However, no sections will be sent back.