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Trial record **1 of 1** for: nct02305043

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Identification of Biomarkers for Prediction of Response or Resistance Against Target Therapy in Gastric Cancer (VARIANZ)

The recruitment status of this study is unknown. The completion date has passed and the status has not been verified in more than two years.

Verified November 2014 by Florian Lordick, MD, University of Leipzig.
Recruitment status was: Recruiting

Sponsor:
University of Leipzig

Collaborator:
German Federal Ministry of Education and Research

Information provided by (Responsible Party):
Florian Lordick, MD, University of Leipzig

ClinicalTrials.gov Identifier:
NCT02305043

First received: November 17, 2014
Last updated: November 27, 2014
Last verified: November 2014
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The aim of this study is to identify biomarkers predicting response or resistance factors of a targeted therapy with trastuzumab in advanced gastric cancer.

Condition	Intervention
Esophageal Neoplasms Stomach Neoplasms	Other: non-interventional

Study Type: Observational [Patient Registry]
Study Design: Observational Model: Cohort
Time Perspective: Prospective
Target Follow-Up Duration: 24 Months

Official Title: Identification of Biomarkers for Prediction of Response or Resistance Against Target Therapy in Adenocarcinoma of the Stomach or Gastroesophageal Junction. A Non-interventional Study

Resource links provided by NLM:

MedlinePlus related topics: Stomach Cancer

Genetic and Rare Diseases Information Center resources: Stomach Cancer Esophageal Cancer

U.S. FDA Resources

Further study details as provided by Florian Lordick, MD, University of Leipzig:

Primary Outcome Measures:

- Percentage of Participants With Objective Response [Time Frame: 12 months]

  Percentage of participants with objective response based assessment of confirmed complete response (CR) or confirmed partial response (PR). CR is defined as the disappearance of all target lesions. PR is defined as at least 30% decrease in the sum of the longest dimension of the target lesion

Secondary Outcome Measures:

- time-to-progression [Time Frame: up to 24 months]

  The period from study entry until disease progression, death, or date of last contact.

- overall survival [Time Frame: up to 24 months]

  OS is the duration from enrollment to death.

Estimated Enrollment:	500
Study Start Date:	March 2014
Estimated Primary Completion Date:	February 2017 (Final data collection date for primary outcome measure)

Intervention Details:

Other: non-interventional

non-interventional

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

patients suffer from histologically proven adenocarcinoma of the stomach or gastroesophageal junction

Criteria

Inclusion Criteria:

- histologically proven adenocarcinoma of the stomach or gastroesophageal junction
  - stage IV
  - patient receives chemotherapy
  - signed informed consent
  - Age > 18 years

Exclusion Criteria:

- Patient can not understand meaning and purpose of the study
- patient already received a chemotherapy treatment for advanced disease.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02305043

Contacts

Contact: Ivonne Haffner, Dr. +49 341 97 12560 Ivonne.Haffner@medizin.uni-leipzig.de

Locations

Germany

University Cancer Center Leipzig **Recruiting**
Leipzig, Germany, 04103

Sponsors and Collaborators

University of Leipzig

German Federal Ministry of Education and Research

Investigators

Principal Investigator: Florian Lordick, Prof. University Cancer Center Leipzig

More Information

Responsible Party:	Florian Lordick, MD, Director University Cancer Center Leipzig, University of Leipzig
ClinicalTrials.gov Identifier:	NCT02305043 History of Changes
Other Study ID Numbers:	VARIANZ
	01ZX1310E (Other Grant/Funding Number: Federal Ministry of Education and Research)
Study First Received:	November 17, 2014
Last Updated:	November 27, 2014

Keywords provided by Florian Lordick, MD, University of Leipzig:
non-interventional
advanced gastric cancer
Trastuzumab
HER2

Additional relevant MeSH terms:

Neoplasms	Digestive System Diseases
Stomach Neoplasms	Gastrointestinal Diseases
Esophageal Neoplasms	Stomach Diseases
Gastrointestinal Neoplasms	Head and Neck Neoplasms
Digestive System Neoplasms	Esophageal Diseases
Neoplasms by Site	

ClinicalTrials.gov processed this record on June 08, 2017