Purpose

Patients with locally advanced resectable adenocarcinoma of the stomach or the esophagogastric junction without previous therapy will be treated with one of two chemotherapy combinations before and after surgery. One half of the patients gets 5-Fluorouracil (5-FU), Leucovorin, Oxaliplatin and Docetaxel (FLOT), the others Epirubicin, Cisplatin and 5-FU (ECF). Main objective of the study is the increase of the pathological complete responses (pCR) with FLOT versus the ECF treatment.

Condition | Intervention | Phase
--- | --- | ---
Gastric Cancer | Drug: 5-Fluorouracil | Phase 2
 | Drug: Leucovorin | Phase 3
 | Drug: Oxaliplatin | 
 | Drug: Docetaxel | 
 | Drug: Epirubicin | 
 | Drug: Cisplatin | 
 | Drug: 5-fluorouracil | 

Resource links provided by NLM:

MedlinePlus related topics: Cancer Stomach Cancer

Drug Information available for: Fluorouracil Leucovorin calcium Cisplatin Epirubicin hydrochloride Epirubicin Cisplatin Oxaliplatin Levoleucovorin Docetaxel

U.S. FDA Resources

Further study details as provided by Krankenhaus Nordwest:

Primary Outcome Measures:
- Disease free survival [Time Frame: 2 years follow-up] [Designated as safety issue: No]

Secondary Outcome Measures:
- Histopathological regression rate [Time Frame: 6 weeks after surgery] [Designated as safety issue: No]
- Overall survival (OS) [Time Frame: 2 years follow-up (maximum 5 years)] [Designated as safety issue: No]
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- correlation of pCR and DFS with survival [Time Frame: 2 years follow-up] [Designated as safety issue: No]
- Perioperative Morbidity and Mortality [Time Frame: up to 2 months after surgery] [Designated as safety issue: Yes]
- R0-Resection rate [Time Frame: 2 months after surgery] [Designated as safety issue: No]

Estimated Enrollment: 590
Study Start Date: July 2010
Estimated Study Completion Date: December 2015
Estimated Primary Completion Date: July 2015 (Final data collection date for primary outcome measure)

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<th>Arms</th>
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| Experimental: FLOT | Drug: 5-Fluorouracil 2600 mg/m² d1 i.v. every 2 weeks  
Drug: Leucovorin 200 mg/m², d1, i.v., every 2 weeks  
Drug: Oxaliplatin 85 mg/m², d1, i.v., every 2 weeks  
Drug: Docetaxel 50mg/m², d1, i.v., every 2 weeks |
| Docetaxel 50mg/m², d1  
5-FU 2600 mg/m², d1  
Leucovorin 200 mg/m², d1  
Oxaliplatin 85 mg/m², d1 every two weeks (q2w) 4 cycles (8 weeks) pre-OP and 4 cycles (8 weeks) post-OP |
| Active Comparator: ECF | Drug: Epirubicin 50 mg/m², d1  
Drug: Cisplatin 60 mg/m², d1  
5-FU 200 mg/m², d1-d21 every 3 weeks (q3w) 3 cycles (9 weeks) pre-OP and 3 cycles (9 weeks) post-OP |
| Epirubicin 50 mg/m², d1  
Cisplatin 60 mg/m², d1  
5-FU 200 mg/m², d1-d21 every 3 weeks (q3w) 3 cycles (9 weeks) pre-OP and 3 cycles (9 weeks) post-OP |

Detailed Description:

590 Patients with locally advanced resectable (T2-4 and/or N+, M0) adenocarcinoma of the stomach or the esophagogastreal junction without previous therapy will be included in this study. After randomization patients receive perioperatively 4 cycles FLOT or 3 cycles ECF, followed by a restaging of the tumour status and surgery. Subsequently another 4 cycles of FLOT or 3 cycles ECF are applicated. Then a central validation of the pathological remission rate is scheduled. Primary endpoint is disease free survival, secondary endpoints are overall survival, perioperative morbidity and mortality, histopathologic regression rate and R0-resection rate.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. locally advanced (>T1) or nodal positive (N+) histologically proven adenocarcinoma of the esophagogastreal junction (AEG I-III) or the stomach without distant metastases (M0) and without infiltration of adjacent structures and organs
2. no previous surgical resection
3. no previous cytostatic chemotherapy
4. Age > 18 years (female and male)
5. ECOG ≤ 2
6. surgical resectability
7. Exclusion of peritoneal carcinomatosis (if clinically suspected) via laparoscopy
8. Leucocytes > 3.000/µl
9. Platelets > 100.000/µl
10. Serum creatinin ≤ 1.5x of normal value, or Creatinin-Clearance > 50 ml/min
11. written informed consent.
12. Ejection fraction > 50% in echocardiography before start of therapy

Exclusion Criteria:

1. distant metastases or infiltration of adjacent structures or organs and all primarily not resectable stages
2. relapse
3. Hypersensitivity against 5-Fluorouracil, Leucovorin, Oxaliplatin, Cisplatin, Epirubicin and Docetaxel
4. Existence of contraindications against 5-Fluorouracil, Leucovorin, Oxaliplatin, Cisplatin, Epirubicin or Docetaxel
5. Active CHD, Cardiomyopathy or cardiac insufficiency stage III-IV according to NYHA
6. Malignant secondary disease, dated back < 5 years (exception: In-situ-carcinoma of the cervix uteri, adequately treated skin basal cell carcinoma)
7. Severe non-surgical accompanying disease or acute infection
8. Peripheral polyneuropathy > NCI Grad II
9. Severe liver dysfunction (AST/ALT>3,5xULN, AP>6xULN, Bilirubin>1,5xULN)
10. Chronic inflammable gastro-intestinal disease
11. Inclusion in another clinical trial
12. Pregnancy or lactation

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01216644

Contacts

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Investigators

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More Information

No publications provided by Krankenhaus Nordwest

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):


Keywords provided by Krankenhaus Nordwest:

- Gastric cancer
- ECF
- FLOT
- Pathological complete remission
- Locally advanced resectable adenocarcinoma of the esophagogastric junction or the stomach

Additional relevant MeSH terms:

- Adenocarcinoma
- Stomach Neoplasms
- Carcinoma
- Neoplasms, Glandular and Epithelial
- Neoplasms by Histologic Type
- Neoplasms
- Gastrointestinal Neoplasms
- Digestive System Neoplasms
- Epirubicin
- Fluorouracil
- Leucovorin
- Levoleucovorin
- Antineoplastic Agents
- Therapeutic Uses
- Pharmacologic Actions
- Radiation-Sensitizing Agents
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