PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Multicenter, Open Lable Phase II Study to Evaluate the Safety and Efficacy of a Perioperative Chemotherapy With Docetaxel, Cisplatin and Capecitabine in Patients With Gastric Adenocarcinoma, Adenocarcinoma of the Gastro-esophageal Junction or the Distal Esophagus

Trial Acronym

DCXAIOCHARITE

URL of the trial

[---]*

Brief Summary in Lay Language

In this study, patients with adenocarcinoma of the stomach, gastro-esophageal junction or the distal esophagus who seem operable with curative intent according to oncological and surgical assessment are treated with 3 preoperative cycles of DCX (Docetaxel, Cisplatin, Capecitabine) followed by surgical resection, followed by 3 postoperative cycles of DCX.

Brief Summary in Scientific Language

Perioperative chemotherapy has been shown to significantly improve the R0 resection rate, the disease free survival and the overall survival in patients with adenocarcinoma of the distal esophagus, the gastro-esophageal junction and the stomach. Therefore perioperative chemotherapy is the new therapeutic standard (Cunningham NEJM 2006, MRC, Lancet 2002, Boige ASCO 2007). The best evaluated regime is the combination of Epirubicin, Cisplatin and 5-FU (ECF) (Cunningham, NEJM 2007). Cisplatin and 5-FU seem to be the most important components forming the backbone of this regime (Boige ASCO 2007).

Docetaxel is a new and highly active agent in gastric cancer. In a randomized phase II study the dual combination of Docetaxel and 5-FU seemed to show similar activity as

ECF,
administered as first line palliative treatment (Thuss-Patience, JCO, 2005). The three drug
combination Docetaxel, Cisplatin, 5-FU has significantly superior efficacy than a
combination of Cisplatin und 5-FU, superior quality of life and significantly superior
overall survival (Van Cutsem, JCO 2007).

It has been shown that Capecitabine the oral prodrug of 5-FU is similarly active as 5-FU and
can replace intravenous 5-FU in combination with Cisplatin in the treatment of gastric
cancer. Capecitabine therefore is FDA approved for gastric cancer (Cunningham, ASCO 2006,
Kang ASCO 2006).

It seems reasonable to optimize perioperative chemotherapy by including modern
chemotherapeutics. The old standard ECF may be improved by integrating Docetaxel und
Capecitabine. By adding Docetaxel to the Cisplatin / flouropyrimidin backbone the efficacy
of the regime may be improved. The replacement of 5-FU by Capecitabine may improve patients´
convenience and possibly effectiveness of the combination. Therefore the 3 drug combination
of Docetaxel, Cisplatin, Capecitabin (DCX) seems to be a highly promising regime regarding
effectiveness and convenience.

In this study patients with adenocarcinoma of the stomach, gastro-esophageal junction or the
distal esophagus who seem operable with curative intent according to oncological and
surgical assessment are treated with 3 preoperative cycles of DCX followed by surgical
resection, followed by 3 postoperative cycles of DCX.

The first application of study medication has to be within 21 days of tumour assessment.
There will be 3 preoperative cycles every 3 weeks. The experimental perioperative regime
evaluated in this study will be Docetaxel/Cisplatin/Capecitabine DCX (75/ 60/ 1875
mg/m2).The operation will be performed 3 to 6 weeks after the end of the third preoperative
chemotherapy cycle (counted from day 21 of cycle 3).

Postoperative chemotherapy will start within 6 - 12 weeks after the operation. 3 weeks after
the end of the last chemotherapy the final investigation (end of study visit) will be done.

Organizational Data

- DRKS-ID: **DRKS00005531**
- Date of Registration in DRKS: **2014/03/11**
- Date of Registration in Partner Registry or other Primary Registry: **2009/03/19**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2008-001849-26**
- Primary Registry-ID: **NCT00865982 (ClinicalTrials.gov)**
- Sponsor-ID: **Eudract-CT-2008-001849-26 (Charite University, Berlin, Germany)**

Health condition or Problem studied

- Free text: **Gastric Cancer**
- Free text: **Esophageal Cancer**
- ICD10: **C15 - Malignant neoplasm of oesophagus**
- ICD10: **C16 - Malignant neoplasm of stomach**

Interventions/Observational Groups

- Arm 1: **Drug: Docetaxel, Cisplatin, Capecitabine**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- R0-resection rate; time frame: After 3 cycles of preoperative chemotherapy (3 month)

Secondary Outcome

- Remission rate according to diagnostic imaging techniques; time frame: After 3 cycles of preoperative chemotherapy (3 month)
- Pathological remission rate; time frame: After 3 cycles of preoperative chemotherapy (3 month)
- Operative and postoperative complication rate; time frame: Within 30 days after surgery
- Resectability rate; time frame: After 3 cycles of preoperative chemotherapy (3 month)
- Rate of local recurrences and metastasis
- Toxicity
- 30-day mortality; time frame: After date of surgery
- Overall survival
- Overall survival rate; time frame: 1,2,3 and 5 years
- Event free survival rate

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **HELIOS-Klinik Bad Saarow, Bad Saarow**
- **Medizinische Klinik mit Schwerpunkt Hämatologie und Onkologie, Charite Campus Virchow Klinikum, Berlin**
- **Medizinische Klinik mit Schwerpunkt Gastroenterologie, Infektiologie und Rheumatologie, Charite Campus Benjamin-Franklin, Berlin**
- **Klinik für Hämatologie, Onkologie und Tumorimmunologie, Charite Campus Buch, Berlin**
- **Klinik für Innere Medizin Abteilung Hämatologie/Onkologie, Städtisches Klinikum Dessau, Dessau**
- **Universitätsklinik und Poliklinik für Innere Medizin IV, Martin Luther Universität Halle-Wittenberg, Halle (Saale)**
- **II. Medizinische Klinik und Poliklinik, Universitätsklinikum Schleswig-Holstein Campus Kiel, Kiel**
- **Internistische Onkologie/ Hämatologie, Städtisches Krankenhaus St. Georg, Leipzig**
- **3. Medizinische Klinik, Onkologisches Zentrum, Universitätsklinikum Mannheim, Mannheim**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2008/09/30**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- Signed and dated consent

- Age between minimum 18 and maximum 75 years

- Primary diagnosis of histologically proven adenocarcinoma of the stomach, the gastro-esophageal junction or an adenocarcinoma of the lower third of the esophagus

- Stage II-III, which is in TNM-staging: T3-4, N0-3, M0 or T2, N1-3, M0 or T1, N2, M0. (equivalent to clinical staging uT3-4NXM0, uT1-2N+M0)

- Intended curative resection according to evaluation of an experienced surgeon

- Karnofsky-performance-index > 70%

- Negative pregnancy blood test at screening but not earlier than 72 hours prior to start of chemotherapy for women with child bearing potential

- Adequate haematologic function and liver and renal function: neutrophils > 1,5 x 109/L; thrombocytes > 100 x 109/L; haemoglobin > 10 g/dl, creatinine clearance > 60 ml/min (calculated according to Cockroft and Gault), total bilirubin < 1,0 x UNL; AST and ALT < 1,5 x UNL, AP < 2,5 x UNL

- Complete staging within 3 weeks prior to start of treatment (CT-scan of thorax and abdomen, endosonography, gastroscopy)

- Ability to keep appointments and follow the study protocol

- By CT-scan, endoscopy or endosonography measurable or evaluable disease

Exclusion criteria

- Former therapy of gastro-esophageal cancer (operation, chemo- or radiotherapy)

- Diagnosis of another cancer in the last 5 years prior to study entry which has not been cured by operation only (exception in-situ-carcinoma of the cervix or cured non-melanomatose skin cancer)

- Known dihydropyrimidine-dehydrogenase (DPD)-deficiency

- Known contraindication to the planned chemotherapeutics

- Presence of distant metastases

- Anamnestic known serious disease or other concomitant diseases that affect participation in this study, such as:

- Instable cardiac disease: symptomatic heart failure, symptomatic coronary artery disease, ventricular cardiac arrhythmia not well controlled with medication, myocardial infarction or resuscitation within 6 month before study

- Active infection necessitating systemic therapy or uncontrolled infection

- Interstitial lung diseases (for example: pneumonitis or fibrosis of the lung) and indication for interstitial lung disease in chest x-ray or CT-scan respectively

- Active inflammatory bowel disease or other bowel diseases which provoke chronic diarrhea (defined as > 4 bowel movements per day)

- Neurological or psychiatric disease including dementia, epilepsy or untreated, symptomatic brain metastases

- Limited hearing ability

- Presence of upper GI obstruction, leading to inability to swallow ground tablets

- Presence of acute or chronic systemic infection

- Presence of a bowel obstruction within the last 30 days

- Pregnant or lactating women or women with child bearing potential and

men without
adequate contraception (high effective contraception, defined as Pearl Index < 1)
like birth control pill, hormone spiral, hormone implant, transdermal patch, a
combination of two barrier methods (condom and diaphragm), realized sterilization or
sexual abstinence during the study and at least for 3 months after the last infusion

- Any other situation which may lead to an unacceptable high risk for the patient, when
he participates in the study

- Parallel treatment in another clinical study or prior participation in this study

- Treatment with any other therapy against the tumor or any parallel radiation

- Parallel treatment with Sorivudine or an chemically related substance like for
example Brivudin

- Symptomatic peripheral neuropathy NCI-CTCAE degree > 2

- Intolerance to the study medication or their galencic ingredients or against 5-FU

- Detention in a psychiatric unit or imprisonment (AMG §40 Abs. 1 Nr. 4)

Addresses

■ **Primary Sponsor**

Charite University, Berlin, Germany

Telephone: **[---]***
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E-mail: **[---]***
URL: **[---]***

■ **Contact for Scientific Queries**

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Peter Thuss-Patience, Dr. med.

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- **Collaborator, Other Address**

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Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 2
- Last processed date by ClinicalTrials.gov: 2014/11/27

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*