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Neoadjuvant chemotherapy in patients with locally advanced and /or nodal positive gastric cancer with Docetaxel, Cisplatin and 5-FU

Submission date 27/07/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/10/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/09/2016	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Gastric cancer is a fairly uncommon type of cancer that develops from the lining of the stomach. Cancer that begins in the stomach and spreads to another part of the body or comes back after treatment is termed advanced stomach cancer. Despite the use of aggressive chemotherapies (medicines that stop cancer cells from dividing and multiplying), the outlook for patients with advanced gastric cancer is rather poor. Even after radical surgery, the overall 5-year survival rate is 20 – 30 % in Europe. Chemotherapy can be given before surgery to try to shrink the tumour so it may then be easier to remove. This type of treatment is called neoadjuvant chemotherapy. The aim of this study is to assess the effectiveness and toxicity (side effects) of neoadjuvant chemotherapy with the drugs docetaxel, cisplatin and 5-FU.

Who can participate?
Patients aged 18 and older with advanced gastric cancer

What does the study involve?
Chemotherapy treatment is given in three cycles, which start on days 1, 22 and 43. For safety monitoring, blood samples are taken on a weekly basis, heart activity is monitored and side effects are recorded. Participants are assessed to see whether the cancer can be fully removed in surgery (curative resection). Side effects and quality of life are also assessed to measure the impact of the disease and chemotherapy on daily life.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Medical University of Greifswald (Germany)

When is the study starting and how long is it expected to run for?
September 2007 to February 2012

Who is funding the study?
Medical University of Greifswald (Germany)

Who is the main contact?
Prof. Julia Mayerle

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
23:07:2007

Study information

Scientific Title
Phase II trial for neoadjuvant chemotherapy in patients with locally advanced and /or nodal positive gastric cancer (UICC stages IIIa, IIIb and IV M0) with Docetaxel, Cisplatin and 5-FU

Acronym
NeoDox

Study objectives
A neoadjuvant chemotherapy in patients with advanced gastric cancer is expected to improve R0 surgical resection and therefore prolong survival of these patients

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee at the Medical Faculty of the University of Greifswald [Ethikkommission an der Medizinischen Fakultät der Universität Greifswald], 26/02/2004, ref: III UV 10/04

Study design
Non-randomised open-label single-group interventional single-centre trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.medizin.uni-greifswald.de/gastro/Studien/magen-ca.htm [German]

Health condition(s) or problem(s) studied
Locally advanced and/or nodal positive gastric cancer (UICC Stages: IIIa, IIIb, IV M0)

Interventions
1. Docetaxel: 75 mg/m2, (infusion, days 1, 22, 43)
2. Cisplatin: 75 mg/m2, (infusion, days 1, 22, 43)
3. 5-FU: 750 mg/(m2 x day), (infusion, days 1-5, 22-26, 43-47)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Cisplatin, docetaxel, 5-FU

Primary outcome measure
Rate of curative (R0) resections after a neoadjuvant chemotherapy

Secondary outcome measures
1. Median survival
2. Median progression-free survival
3. Remission rate
4. Toxicity of the protocol
5. Quality of life during neoadjuvant chemotherapy

Overall study start date
01/09/2007

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. Locally advanced and/or node positive gastric adenocarcinoma (UICC stages IIIa, IIIb, IV and M0)
2. Aged 18 years and older
3. Eastern Cooperative Oncology Group Performance Status (ECOG PS): 0 - 2
4. Adequate organ function
5. Signed informed consent
6. Participants: patients of both genders, no healthy volunteers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
46

Key exclusion criteria
1. Metastatic disease
2. Prior chemotherapy for gastric cancer
3. Tumour recurrence after gastrectomy
4. Estimated life expectancy < 3 months
5. Presence of any serious concomitant systemic disorder

Date of first enrolment
01/09/2007

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
Germany

Study participating centre

Medical University of Greifswald
Greifswald
Germany
17475

Sponsor information

Organisation
Medical University of Greifswald (Germany)

Sponsor details
Fleischmannstraße 8
Greifswald
Germany
17475

Sponsor type
University/education

Website
http://www.medizin.uni-greifswald.de/

ROR
https://ror.org/00r1edq15

Funder(s)

Funder type
University/education

Funder Name
Medical University of Greifswald (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration