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A randomized phase II trial comparing epirubicin, cisplatin, and capecitabine versus the combination of epirubicin, cisplatin, and capecitabine with pravastatin in patients with irresectable or metastatic gastric carcinoma

Submission date
27/01/2006

Recruitment status
No longer recruiting

Registration date
27/01/2006

Overall study status
Completed

Last Edited
06/07/2009

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR416; EMC 04-147

Study information

Scientific Title

Acronym
ECC

Study objectives
Treatment with capecitabine, combined with epirubicin and cisplatin (ECC) has been proven to improve time to progression and survival in patients with advanced, non-resectable gastric cancer. HMG-CoA-reductase inhibitors have anti-tumor activity in vitro against gastric carcinoma. Statins furthermore interact synergistically with cisplatin, 5-FU and doxorubicin both in vitro and animal models. As prognosis of advanced irresectable gastric cancer is poor, it is worthwhile to study whether the combination of ECC and pravastatin is an option for these patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastric carcinoma

Interventions
Control arm (ECC): epirubicin 50 mg/m2 iv, day 1, Cisplatin 60 mg/m2 iv, day 1, 3-hour infusion, Capecitabine 1000 mg/m2 in the morning and 1000 mg/m2 in the evening, po, day 1-14. ECC will be given at 3-week intervals, for a maximum total of 6 cycles.
Experimental arm (ECC plus pravastatin): Epirubicin 50 mg/m2 iv, day 1, Cisplatin 60 mg/m2 iv, day 1, 3-hour infusion, Capecitabine 1000 mg/m2 in the morning and 1000 mg/m2 in the evening, po, day 1-14. ECC will be given at 3-week intervals, for a maximum total of 6 cycles. In addition, patients will receive daily 40 mg pravastatin, from day 1 to 1 week after the capecitabine of the last ECC.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
capecitabine, epirubicin, cisplatin, pravastatin

Primary outcome(s)
Progression free survival rate (PFR) after 6 months.

Key secondary outcome(s))
1. Response rate scored according to the RECIST criteria
2. Overall survival
3. Quality of life
4. Toxicity graded according the international 'Common Toxicity Criteria'

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Histologically proven, irresectable gastric adenocarcinoma, except carcinoma of the cardia
2. WHO 0-2
3. Ability to swallow
4. Adequate hepatic, renal and bone marrow function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Prior chemotherapy or radiotherapy
2. Current treatment with HMG-CoA-reductase inhibitor
3. Peripheral neurotoxicity grade >2

Date of first enrolment
01/02/2005

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus MC - Daniel den Hoed
Rotterdam
Netherlands
3075 EA

Sponsor information

Organisation
Erasmus Medical Center, Department of Medical Oncology (Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Center (Netherlands)

Alternative Name(s)
Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration