

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/07/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Progression free survival rate (PFR) after 6 months.

Secondary outcome measures

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'

Overall study start date

01/02/2005

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

43

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)

Sponsor details

P.O. Box 5201

Rotterdam

Netherlands

3008 AE

Sponsor type

Hospital/treatment centre

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

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