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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27982

Source
Nationaal Trial Register

Brief title
ECC

Health condition

advanced irresectable or metastatic gastric carcinoma

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Progression free survival rate (PFR) after 6 months.

Secondary outcome

Response rate scored according to the RECIST criteria, overall survival, quality of life, and toxicity graded according the international “Common Toxicity Criteria”.

Study description

Background summary

N/A

Study objective

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.

Intervention

Control arm (ECC): epirubicin 50 mg/m2 i.v., day 1, Cisplatin 60 mg/m2 i.v., day 1, 3-hour infusion, Capecitabine 1000 mg/m2 in the morning and 1000 mg/m2 in the evening, p.o., 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 i.v., day 1, Cisplatin 60 mg/m2 i.v., day 1, 3-hour infusion, Capecitabine 1000 mg/m2 in the morning and 1000 mg/m2 in the evening, p.o., 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.

Contacts

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Eligibility criteria

Inclusion criteria

Histologically proven, irresectable gastric adenocarcinoma, except carcinoma of the cardia, WHO 0-2, ability to swallow, adequate hepatic, renal and bone marrow function.

Exclusion criteria

Prior chemotherapy or radiotherapy, current treatment with HMG-CoA-reductase inhibitor, peripheral neurotoxicity grade >2.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2005
Enrollment:	43
Type:	Anticipated

Ethics review

Positive opinion Date:	20-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL376
NTR-old	NTR416
Other	: EMC 04-147
ISRCTN	ISRCTN23062732

Study results

Summary results
N/A