

Chemotherapy +/- vitamin supplementation in advanced Oesophagogastric cancer

Submission date 27/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/01/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/08/2009	Condition category Cancer	☐ 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
NTR470

Study information

Scientific Title

Acronym

Vitamine study

Study objectives

Primary objective: Does supplementation of vitamins to the combination of gemcitabine and cisplatin increase the response rate in patients with oesophagogastric cancer?

Secondary objectives:

1. To assess the relationship between plasma homocysteine and plasma folic acid concentrations
2. To assess whether genetic polymorphisms in folate metabolising enzymes are related to folate homeostasis and efficacy
3. To determine the relationship between response and biomarkers for either gemcitabine and cisplatin
4. To determine whether vitamin supplementation affects pharmacokinetics of gemcitabine and cisplatin
5. To assess the time to progressive disease and overall survival
6. To assess the hematopoietic response of darbepoetin alfa

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oesophagogastric cancer

Interventions

Group A: patients will be treated with gemcitabine 1250 mg/m² IV on days 1 and 8 in combination with Cisplatin 80 mg/m² on day 1 with vitamin supplementation (Folic acid 450 ug /24 hours PO, starting at least one week prior to chemotherapy and finishing at least 3 weeks after the last treatment dose. Vitamin B12 1000 ug approximately every 9 weeks, starting 1 week before chemotherapy and finishing at least 3 weeks after the last treatment dose).

Group B: patients will be treated with gemcitabine 1250 mg/m² on days 1 and 8 in combination with Cisplatin 80 mg/m² on day 1 without vitamin supplementation. Cycles will be administered every 21 days. A maximum of 6 cycles will be administered to every patient, although this number could be increased if the patient may benefit from it, based on investigator's criteria.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Response rate

Key secondary outcome(s)

1. Time to progression
2. Overall survival

Completion date

01/03/2006

Eligibility

Key inclusion criteria

1. Patients must have histologically or cytologically confirmed metastatic or locally advanced unresectable advanced oesophagogastric carcinoma (squamous or adenocarcinoma), not amenable for curative treatment
2. Patients may have received prior surgery, and chemotherapy and/or radiotherapy in neo-adjuvant or adjuvant setting as long as the chemotherapy was completed at least 6 months prior to study entry
3. Patients should have measurable disease according to RECIST criteria
4. Age of at least 18
5. Performance status (ECOG) 0, 1 or 2
6. Life expectancy of at least 12 weeks
7. Adequate bone marrow function, defined by a neutrophil count above $1.5 \times 10^9/l$, platelet count above $100 \times 10^9/l$ and hemoglobin above 5.6 mmol/l
8. Adequate renal and hepatic function, defined by bilirubin $<1.5 \times$ upper limit of normal (ULN), alkaline phosphatase (AP), aspartate transaminase (AST) and alanine transaminase (ALT) $<3 \times$ ULN ($<5 \times$ ULN is acceptable in case of liver metastasis) and creatinine $<120 \mu\text{mol/l}$ and/or creatinine clearance $>60 \text{ ml/min}$ (calculated by using the Cockcroft and Gault formula)
9. Patients must not already be taking vitamin supplements as defined in the protocol
10. Patients with childbearing potential must use an adequate contraceptive method
11. Patients must be able to comply with protocol procedures, able to swallow pills and have adequate geographical proximity to the study site
12. Patients must sign written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Active infection or cardiac disease, at the investigators criteria
2. Pregnancy or breast-feeding
3. Known symptomatic metastasis in the central nervous system (CNS)
4. Treatment with any investigational agent in the month prior to inclusion
5. Other serious disease, at the investigators discretion
6. Prior diagnosis of other malignant disease, excluding adequately treated in situ carcinoma of the cervix and skin cancer other than melanoma, low grade prostate carcinoma (gleason score <6) or any other non-relapsed malignancy that was treated more than five years before diagnosis
7. Received any RBC transfusions within 14 days before first dose of Aranesp or received rHuEPO or darbepoetin alfa therapy within 4 weeks before study day 1

Date of first enrolment

01/03/2004

Date of final enrolment

01/03/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

VU Medical Center

Amsterdam

Netherlands

1007 MB

Sponsor information

Organisation

VU University Medical Centre (Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Industry

Funder Name

Eli Lilly Nederland B.V. (Netherlands)

Funder Name

Amgen B.V. (Netherlands)

Funder Name

VU University Medical Center (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration