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# Chemotherapy +/- vitamin supplementation in advanced Oesophagogastric cancer

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 27/01/2006 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 27/01/2006 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 12/08/2009 | Cancer | [ ] 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 x 10^9/l, platelet count above 100 x 10^9/l and hemoglobin above 5.6 mmol/l
8. Adequate renal and hepatic function, defined by bilirubin <1.5 x upper limit of normal (ULN), alkaline phosphatase (AP), aspartate transaminase (AST) and alanine transaminase (ALT) <3 x ULN (<5 x ULN is acceptable in case of liver metastasis) and creatinine <120 umol/l and/or creatinine clearance >60 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