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Chemoradiation for irresectable (T4) oesophageal cancer: a phase II multicentre study

Submission date	Recruitment status	[_] Prospectively registered
27/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/08/2021	Cancer	

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
EMC 03-092 (CKTO2004-02), NL370 (NTR410)

Study information

Scientific Title
Chemoradiation for irresectable (T4) oesophageal cancer: a phase II multicentre study

Acronym
T4

Study objectives
Chemoradiation therapy for irresectable T4 oesophageal tumour improves response rate and survival compared to radiotherapy alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received by the Medical Ethics Committee of Erasmus University Hospital on the 30th October 2003 (ref: EMC 03-092).

Primary study design
Interventional

Study design
Phase II, non-randomised, non-controlled, multicentre study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Oesophageal cancer

Interventions
Paclitaxel 50mg/m^2 and carboplatin Area Under the Curve (AUC) equals two on days one, eight, 15, 22, 29 and 36. A total of 50.4 Gy will be given in 28 fractions of 1.8 Gy, five fractions per week, starting on the first day of chemotherapy.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Paclitaxel and carboplatin

Primary outcome(s)
1. To determine clinically complete biopsy proved response rate after a chemotherapy regime for patients with locally irresectable carcinoma of the oesophagus or gastric junction without distant metastases (stage T4 N0-1 MO)
2. To evaluate toxicity of this chemotherapy regimen in this group of patients

Key secondary outcome(s)
1. To determine Time To Progression (TTP) of the disease after treatment
2. To determine quality of life before, during and after treatment
3. To obtain insight in survival after treatment

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. T4 N0-1 M0
2. Tumour length less than 10 cm
3. Upper tumour border 2 cm of upper oesophageal sphincter
4. Tumour must not extend more than 4 cm into the stomach
5. World Health Organisation (WHO) grade zero to two
6. Adequate haematological, renal, hepatic and pulmonal function
7. Adequate caloric- and/or fluid intake

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
54

Key exclusion criteria
1. Previous chemotherapy and or radiotherapy on mediastinum or upper abdomen
2. Myocardial Infarction (MI) within last six months
3. Ventricular arrhythmia or congestive heart failure
4. Second or third degree heart blocks
5. Pre-existing neurotoxicity more than grade one
6. Active infection

Date of first enrolment
30/10/2003

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Centre (The Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Government

Funder Name
Commission for Medical Applied Research (Commissie voor Klinisch Toegepast Onderzoek [CKTO]) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/05/2006	26/08/2021	Yes	No