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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
27/02/2007		☐ 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

#### Contact name

Dr A van der Gaast

#### Contact details

Erasmus Medical Centre
Department of Medical Oncology
P.O. Box 2040
Dr. Molewaterplein 40
Rotterdam
Netherlands
3000 CA
+31 (0)10 463 4897
a.vandergaast@erasmusmc.nl

# Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

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).

#### Study design

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

#### Primary study design

Interventional

# Secondary study design

Multi-centre

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

# 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 measure

- 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

#### Secondary outcome measures

- 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

#### Overall study start date

30/10/2003

#### 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** 

#### Age group

**Not Specified** 

#### Sex

Not Specified

#### Target number of participants

43

#### 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)

#### Sponsor details

P.O. Box 2040 Rotterdam Netherlands 3000 CA

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.erasmusmc.nl/

#### **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**

# 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

# **Study outputs**

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