ISRCTN80832026 https://doi.org/10.1186/ISRCTN80832026

Neoadjuvant chemoradiation followed by surgery versus surgery alone for patients with adenocarcinomas or squamous cell carcinomas of the esophagus

Submission date
27/01/2006

Recruitment status
No longer recruiting

Registration date
27/01/2006

Overall study status
Completed

Last Edited
02/07/2009

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR487; EMC 03-209 (CKTO 2004-13)

Study information

Scientific Title

Acronym
CROSS II

Study objectives
Surgery is the standard therapy for esophageal cancer. However, 30% of the resections are irradical. It is thought that preceding chemoradiotherapy will improve the surgery results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Multicentre randomised active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Paclitaxel 50 mg/m2 and carboplatin AUC = 2 on days 2, 8, 15, 22 and 29.
Radiotherapy will start on day 1 of chemotherapy. A total of 41.4 Gy, 23 fractions of 1.8 Gy, 5 fractions a week.
Surgery (if randomised in this arm) will preferably be performed within 6 weeks after completion of chemoradiation.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
1. To compare median survival rates between patients treated for surgical resectable esophageal adenocarcinoma or squamous cell carcinoma
2. To compare quality of life before, during and after treatment

Secondary outcome measures
1. To compare pathological responses
2. Progression free survival
3. Number of R0 resections
4. Treatment toxicity
5. Costs

Overall study start date
18/03/2004

Completion date
01/01/2006

Eligibility

Key inclusion criteria
1. Age >18, <75 years
2. Surgical resectable T2-3, N0-1, M0
3. Tumour length longitudinal <8 cm and radial <5 cm
4. No invasion tracheobronchial tree
5. Tumour must not extend more than 2 cm into the stomach
6. ECOG 0-2

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
350

Key exclusion criteria
1. T1N1
2. T1N0
3. Past or current history of malignancy other than entry diagnosis

4. Previous chemotherapy or radiotherapy
5. MI in last 6 months
6. Congestive heart failure or arrhythmia requiring medication
7. Neurotoxicity grade >1
8. Inadequate caloric and or fluid intake
9. Weight loss 10%

Date of first enrolment
18/03/2004

Date of final enrolment
01/01/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3008 AE

Sponsor information

Organisation
Erasmus Medical Center, Department of Medical Oncology (Netherlands)

Sponsor details
P.O. Box 5201
Rotterdam
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3008 AE

Sponsor type
Not defined

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
Dutch Cancer Society (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	result	01/06/1991		Yes	No