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Chemotherapy Followed by Surgery versus Surgery Alone in Patients with Oesophageal Squamous Cell Carcinoma

Submission date	Recruitment status	[_] Prospectively registered
23/08/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/08/2021	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Chemotherapy Followed by Surgery versus Surgery Alone in Patients with Oesophageal Squamous Cell Carcinoma: Long-term Results of a Randomised Controlled Trial

Study objectives
Patients with oesophageal sqaumous cell carcinoma who receive preoperative chemotherapy have equal or better overall survival compared to patients who undergo surgery alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study protocol was approved by the Ethics Committee of all participating institutions, and by the Review Board of the Netherlands Cancer Foundation

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Oesophageal squamous cell carcinoma

Interventions
Random assignment was stratified by age, gender, weight loss in the past four months and length of the tumor as measured by esophago-gastroscopy.
Patients assigned to preoperative chemotherapy (CS group) received neoadjuvant etoposide plus cisplatin. Cisplatin, at a dose of 80 mg/m2, was given intravenously over 4 hours on day one of each cycle preceded and followed by adequate hydration. Etoposide, at a dose of 100 mg/m2, was administered intravenously over 2 hours on day 1 (before cisplatin) and day 2, followed by etoposide 200 mg/m2 orally on days 3 and 5. This course was repeated in week 4. In case of clinical response, two subsequent courses of chemotherapy were administered in week 8 and 11. Surgery was performed between 4 and 6 weeks after the last course of chemotherapy.

Patients assigned to surgery alone (S group) recieved surgery as soon as possible.

Surgery protocol for both treatment groups:
For carcinomas of the upper half of the intra-thoracic esophagus a right-sided thoracotomy was performed. For carcinomas of the lower half of the intra-thoracic esophagus a transhiatal esophagectomy was preferred. The tumor and its adjacent lymph nodes were dissected en bloc. The left gastric artery was transected at its origin, with resection of local lymph nodes. The continuity of the digestive tract was restored by means of gastric tube reconstruction or colonic interposition with a cervical anastomosis.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Overall survival

Secondary outcome measures
Disease free survival

Overall study start date
01/01/1989

Completion date
01/01/1996

Eligibility

Key inclusion criteria
1. Histologically confirmed squamous cell carcinoma of the intra-thoracic oesophagus
2. No evidence of distant metastases
3. Absence of unresectable local disease
4. Below 80 years of age
5. In adequate physical condition (Karnofsky score >70) to undergo surgery
6. Adequate hepatic, renal and bone marrow function

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
160

Total final enrolment

Key exclusion criteria
1. Synchronous cancer
2. Tumour localization in the cervical oesophagus (upper border, <18 cm from the incisor teeth)
3. Severe cardiovascular or pulmonary disease
Patients with previous malignancies were eligible if more than 5 years had elapsed from diagnosis without evidence of tumor recurrence; exceptions were made for adequately treated basal cell cancer of the skin or carcinoma in situ of the cervix.

Date of first enrolment
01/01/1989

Date of final enrolment
01/01/1996

Locations

Countries of recruitment
Netherlands

Study participating centre
Dr Molewaterplein 50
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Dr Molewaterplein 50
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Medical Centre (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

1997 results in Kok TC, van Lanschot JJB, Siersema PD, van Overhagen HV, Tilanus HW. Neoadjuvant chemotherapy in operable esophageal squamous cell cancer: final report of a phase III multicenter randomized controlled trial. Proc Am Soc Clin Oncol. 1997; 17:984.

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		19/05/2011	05/08/2021	Yes	No