CROSS II.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20325

Source
NTR

Brief title
CROSS II

Health condition

Esophageal cancer.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Dutch Cancer Society.

Intervention

Outcome measures

Primary outcome

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

1. To compare pathological responses;

2. Progression free survival;

3. Number of R0 resections;

4. Treatment toxicity;

5. Costs.

Study description

Background summary

N/A

Study objective

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.

Study design

N/A

Intervention

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 be preferably be performed within 6 weeks after completion of chemoradiation.

Contacts

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Eligibility criteria

Inclusion criteria

18 < age < 75 year, surgical resectable T2-3, N0-1, M0, tumour length longitudinal <8cm and radial <5cm, no invasion tracheobronchial tree, tumour must not extend more than 2 cm into the stomach, ECOG 0-2.

Exclusion criteria

T1N1, T1N0, past or current history of malignancy other than entry diagnosis, previouw chemotherapy or radiotherapy, MI in last 6 months, congestive heart failure or arrhythmia requiring medication, neurotoxicity grade >1, inadequate caloric and or fluid intake, weight loss 10%.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2004
Enrollment:	350
Type:	Actual

Ethics review

Positive opinion

Date:	16-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL447
NTR-old	NTR487
Other	: EMC 03-209 (CKTO 2004-13)
ISRCTN	ISRCTN80832026

Study results

Summary results

N/A