Chemoradiation for irresectable (T4) esophageal cancer, a phase II multicenter study.

No registrations found.

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

Summary

ID

NL-OMON20123

Source
Nationaal Trial Register

Brief title
T4

Health condition

Esophageal cancer

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

To determine clinically complete biopsy proved response rate after a chemotherapy regime for patients with locally irresectable carcinoma of the esophagus or gatric junction without distant metastases (stage T4N0-1MO).

To evaluate toxicity of this chemotherapy regimen in this group of patients.

Secondary outcome

To determine time to progression (TTP) of the disease after treatment. To determine quality of life before, during and after treatment. To obtain insight in survival after treatment.

Study description

Background summary

N/A

Study objective

Chemoradiation therapy for irresectable T4 esophageal tumor improves response rate and survival compared to radiotherapy alone.

Study design

N/A

Intervention

Paclitaxel 50mg/m2 and carboplatin AUC=2 on days 1, 8, 15, 22, 29 and 36.
A total of 50.4 Gy will be given in 28 fractions of 1.8Gy, 5 fractions per week, starting on the first day of chemotherapy.

Contacts

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Eligibility criteria

Inclusion criteria

1. T4N0-1M0;

2. tumour length <10 cm;

3. upper tumour border 2 cm of upper esophageal sphincter;

4. tumor mus not extend more than 4 cm into the stomach;

5. WHO 0-2;

6. adequate haematological, renal, hepatic and pulmonal function, adequate caloric- and/or fluid intake.

Exclusion criteria

1. Previous chemotherapy and or radiotherapy on mediastinum or upper abdomen;

2. MI within last 6 months;

3. ventricular arrhythmia or congestive heart failure;

4. second or third degree heart blocks;

5. pre-existing neurotoxicity grade >1;

6. active infection.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2003
Enrollment:	43
Type:	Actual

Ethics review

Positive opinion

Date:	19-09-2005
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	NL370

Register	ID
NTR-old	NTR410
Other	: EMC 03-092 (CKTO2004-02)
ISRCTN	ISRCTN15521056

Study results

Summary results
N/A