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Accuracy of FDG-PET and spiral CT for the early prediction of non-response to preoperative chemoradiotherapy in patients with oesophageal cancer

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
10/08/2009

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR253

Study information

Scientific Title

Acronym
NEOPEC

Study objectives
To compare FDG-PET and CT-scan for the early prediction of non-response to preoperative chemoradiotherapy in patients with potentially curable oesophageal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
150 consecutive patients will be included in this prognostic accuracy study over a 3 year period. FDG-PET and CT-scan will be performed independently before and 2 weeks after the start of the chemo radiotherapy.
All patients complete the 5 weeks regimen of neoadjuvant chemo radiotherapy, regardless the test results.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The accuracy of serial FDG-PET and CT-scan for the early prediction of response versus non-response to preoperative chemoradiotherapy. The negative predictive value of serial FDG-PET and CT-scan for non-response.
These primary endpoints will quantify the diagnostic potential and clinical applicability / usefulness of each technique to predict early treatment response.

Key secondary outcome(s))
The correlation between histological tumor response in the resection specimen and long term survival.

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Histologically proven squamous cell carcinoma, adenocarcinoma or undifferentiated carcinoma of the intrathoracic oesophagus.
2. Surgical resectable (T2-3, N0-1, M0), as determined by Endoscopic Ultra Sound (EUS).
3. T1N1 are eligible. (T1N0 tumors and tumors in situ are not elligible).
Tumor length longitudinal <8 cm and radial < 5 cm
4. If the tumor extends below the gastroesophageal(GE) junction into the proximal stomach, the bulk of the tumor must involve the oesophagus or GE junction. The tumor must not extend > 2 cm into the stomach. Gastric cancers with minor involvement of the GE junction or distal esophagus are not eligible.
5. No invasion of the tracheobronchial tree or presence of tracheoesophageal fistula.
6. Non pregnant, non-lactating female patients. Sexually active patients of childbearing potential must implement effective contraceptive practices during the study when treated with chemotherapy.
7. Age <18 and >75
8. ECOG performance status of 0-2
9. Granulocytes > 1.5 x 109/l
10. Platelets > 100 x 109/l
11. Total bilirubin < 1.5 x ULN
12. Creatinine <120 µmol/L
13. FEV1 > 1,5 L
14. Written, voluntary informed consent.
15. Patients must be accessible to follow up and management in the treatment center.
16. Patients must sufficiently understand the Dutch language to fill in quality of life questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Past or current history of malignancy other than entry diagnosis except for non-melanomatous skin cancer, or curatively treated carcinoma in situ of the cervix or a cured" malignancy more than 5 years prior to enrollment
2. Previous chemotherapy and radiotherapy
3. New York Heart Association Class lll/lV and no history of active angina
4. Documented myocardial infarction within 6 months preceding registration (pretreatment ECG evidence of infarct only will not exclude patients)
5. Patients with a history of significant ventricular arrhythmia requiring medication or congestive heart failure History of 2nd or 3rd degree heart blocks
6. Pre-existing motor or sensory neurotoxicity greater than WHO grade 1
7. Active infection or other serious underlying medical condition which would impair the ability of the patient to receive the planned treatment, including prior allergic reactions to drugs containing Cremophor, such as teniposide or cyclosporin
8. Dementia or altered mental status that would prohibit the understanding and giving of informed consent
9. Inadequate caloric- and/ or fluid intake
10. Weight loss > 10%

Date of first enrolment
01/01/2005

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

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?
Protocol article	Protocol	31/07/2008		Yes	No