Genetic and protein profiling in patients with oesophageal cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19982

Source
Nationaal Trial Register

Brief title
PROFOC

Health condition

oesophageal neoplasms
protein profiling
gene expression profiling
neoadjuvant treatment

Intervention

Outcome measures

Primary outcome

The following comparisons will be performed:

1. Patients who are diagnosed with metastatic disease within 1 year after diagnosis versus patients without metastatic disease within 1 year after diagnosis;

2. Patients in whom the tumour shows partial or complete response to preoperative or definitive chemoradiotherapy versus patients in whom the tumour is unresponsive to this

type of treatment.

Secondary outcome

N/A

Study description

Background summary

Rationale:

To investigate whether gene expression profiling and serum protein profiling can improve individual treatment planning in patients who present with non-metastatic oesophageal cancer. And, to provide further insight into genetic pathways that underlie the processes of tumour dissemination, and the response to chemoradiation in patients with locally advanced oesophageal cancer.

Methodology:

In a prospective study including patients with non-metastatic oesophageal cancer, the following methods will be applied:

1. Genome-wide gene expression profiling with microarray technology in biopsy samples and surgical specimens;

2. Protein profiling in serum samples using Matrix-assisted laser desorption/ionisation-time of flight mass spectrometry (MALDI-TOF MS).

Objectives:

Microarray:

1. To identify a tumour genetic profile that is associated with early metastatic spread in patients presenting with oesophageal cancer and no evidence of distant metastasis at the time of diagnosis;

2. To distinguish oesophageal cancer patients who will respond to chemoradiotherapy from those who will not respond with the use of gene expression profiling.

Proteomics:

3. To identify distinctive protein profiles in serum samples that can discriminate between subgroups of patients with oesophageal cancer (those with early metastatic spread versus those without, and responders versus non responders to chemoradiation);

4. To investigate whether serum protein profiling reflects tumour activity in patients who are treated for oesophageal cancer.

Study objective

Microarray:

1. To identify a tumour genetic profile that is associated with early metastatic spread in patients presenting with oesophageal cancer and no evidence of distant metastasis at the time of diagnosis;

2. To distinguish oesophageal cancer patients who will respond to chemoradiotherapy from those who will not respond with the use of gene expression profiling.

Proteomics:

3. To identify distinctive protein profiles in serum samples that can discriminate between subgroups of patients with oesophageal cancer (those with early metastatic spread versus those without, and responders versus non responders to chemoradiation);

4. To investigate whether serum protein profiling reflects tumour activity in patients who are treated for oesophageal cancer.

Study design

Tissue specimens of oesophageal tumours are routinely removed from patients during gastroduodenoscopy. Tissue specimens will also be obtained from normal oesophageal mucosa. This poses no significant additional risk to the patient. If only EUS is warranted, a diagnostic endoscopy is added to the procedure for tissue sampling.

For protein profiling a 10 ml-blood sample is required from study participants. The first sample will be drawn prior to the start of the study.

Additional blood samples will be drawn at different time points during the course of the therapy:

1. In patients undergoing (neoadjuvant) chemoradiotherapy, two weeks after the start of the

treatment and at the end of the treatment;

2. And, in patients undergoing surgery, at postoperative day 1 and four weeks after the operation.

This blood sampling for research will be combined with blood sampling for routine clinical practice.

Intervention

Burden associated with participation:

1. Extra biopsies (6) during planned gastroduodenoscopy/endoscopic ultrasonography before the start of therapy;

2. Five blood withdrawals (combined with planned blood withdrawals during therapy):
One sample will be drawn directly before gastroduodenoscopy/endosonography.
Additional blood samples will be drawn at different time points during the course of the therapy:
In patients undergoing (neoadjuvant) chemoradiotherapy, two weeks after the start of the treatment and at
the end of the treatment.
And, in patients undergoing surgery, at postoperative day 1 and four weeks after the operation;

3. Individual duration of the study will be 4 months (from planned gastroduodenoscopy/endoscopic ultrasonography until four weeks after the operation).

Contacts

Public
E. Courrech Staal
Plesmanlaan 121

Amsterdam 1066 CX
The Netherlands
+31 (0)20 5122954
Scientific
E. Courrech Staal
Plesmanlaan 121

Amsterdam 1066 CX
The Netherlands
+31 (0)20 5122954

Eligibility criteria

Inclusion criteria

1. Patients presenting at the NKI-AvL or LUMC for the treatment of oesophageal cancer;

2. Planned gastroduodenoscopy (for diagnosis, feeding tube insertion, dilatation, etc.) or endoscopic ultrasonography (for staging) before the start of therapy;

3. No evidence of distant metastases at presentation (by endoscopic ultrasonography, computer tomography, and positron emission tomography);

4. Able and willing to undergo blood and/or tissue sampling for research activities;

5. Age > 18 years.

Exclusion criteria

1. Any condition that prohibits safe biopsy sampling (e.g. use of anticoagulants);

2. Incapacity or unwillingness to give written informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2008

Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion
Date: 25-05-2009
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32169
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1722
NTR-old	NTR1832
CCMO	NL22892.031.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON32169

Study results

Summary results
N/A