MARKERS OF RESPONSE TO CHEMORADIATION IN ESOPHAGEAL CANCER
Selection and validation of a panel of markers (MORE-1 and MORE-2)

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The objective of the MORE studies is to select and validate a biomarker profile predictive for the response to weekly paclitaxel and carboplatin chemotherapy concomitant with radiotherapy in patients with esophageal cancer.In the MORE-1 pilot study...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON42549

Source
ToetsingOnline

Brief title
MORE

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting De Friesland

Intervention

Keyword: Biomarker, Esophageal cancer

Outcome measures

Primary outcome

The main study parameters are differences in kinetic profile and/or genetic profile between patients with and without a pathologic complete response after chemo radiation.

Primary endpoint for evaluation in the MORE-1 study is pathologic complete response in the resected material.

Primary endpoint for evaluation in the MORE-2 study is survival

Secondary outcome

Secundary endpoints for evaluation in the MORE-1 study are pathological response, locoregional disease free survival, distant metastasis free survival, disease free survival and survival.

Secundary endpoints for evaluation in the MORE-2 study are locoregional disease free survival, distant metastasis free survival and disease free survival.

Study description

Background summary

In the Netherlands chemo radiation followed by surgery is the standard treatment regimen for patients with resectable esophageal cancer. The addition of chemo radiation does improve the median 5 year survival with absolute 13% to 47%. Thirty percent of patients has a pathological complete response after chemo radiation. This observation implies that avoiding surgery can become an option in those patients whose tumor responds very well to chemo radiation. There is a need for adequate prognostic and predictive information available before start of treatment in order to tailor treatment modalities (personalized medicine).
Besides from morphological type (squamous cell carcinomas have a better response than adeno carcinomas), there are no validated clinical markers, pathological markers or biomarkers available that adequately predict the response to chemo radiation. A multimodal approach, combining genomics and proteomics will probably improve the possibilities to define and validate a set of predictive biomarkers successfully.

Study objective

The objective of the MORE studies is to select and validate a biomarker profile predictive for the response to weekly paclitaxel and carboplatin chemotherapy concomitant with radiotherapy in patients with esophageal cancer.
In the MORE-1 pilot study candidate biomarkers are selected using a multimodal approach combining genomics (next generation sequencing) and proteonomics/kinomics (kinase activity profiling). The first cohort of 30 patients is used for the selection of biomarkers, the second cohort of 30 patients for validation.
The objective of the MORE-2 study is to validate the classifier that is developed in the MORE-1 study in patients treated with definitive chemo radiation (without surgery).

Study design

A prospective, single-center pilot study, performed in Leeuwarden Medical Center (MCL).

Study burden and risks

Extra biopsies will be taken from de esophageal tumor by endoscopy. The endoscopic procedure is combined with the regular endoscopic ultrasonography procedure. Diagnostic upper gastrointestinal endoscopy is a safe procedure. The estimated overall complication rate (including biopsies) is 0,13% with an associated mortality of 0,004%. One extra blood sample will be taken from the patient combined with a routine blood collection.

Contacts

Public
Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8934 AD
NL
Scientific
Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8934 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Esophageal cancer with an indication for chemotherapie, radiotherapie with orwithout surgery with curative intention

Exclusion criteria

Metastatic disease

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2016
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO

Date:	30-07-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23044
Source: NTR
Title:

In other registers

Register	ID
Other	22490
CCMO	NL53633.099.15
OMON	NL-OMON23044