Response evaluation after chemoradiation for advanced oropharyngeal cancer using PET-CT and MRI

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26306

Source
NTR

Brief title
REACTION

Health condition

Squamous cell carcinoma (SCC), oropharynx

Sponsors and support

Primary sponsor: Prof. dr. R. de Bree.
Afdeling Keel-, Neus-, en Oorheelkunde/ Hoofd-halschirurgie
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Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary endpoint is: accuracy with which diagnostic tests reduce the number of avoided futile EUAs.

Secondary outcome

Secondary endpoints are: interobserver agreement, SUV (FDG-PET) and ADC (DW-MRI) thresholds, associated costs and burden of diagnostic procedures and health related quality of life.

Study description

Background summary

Rationale: Current clinical practice is to perform response evaluation, i.e. examination under general anesthesia (EUA), routinely at 3 months after the end of treatment in patients who underwent chemoradiation for oropharyngeal cancer. Due the high response rates more than half of the patients are exposed to unnecessary biopsies. Biopsies in previously irradiated areas may induce complaints, e.g. pain, inflammation, wound healing problems, swallowing, dyspnea. Biopsies in previously treated areas may be false negative due to sampling errors within the residual mass. Besides aforementioned burden to the patient, such a examination under general anesthesia (EUA) requires hospital stay and operating facilities.

Objective: To study the value of MRI and 18FDG-PET-CT in the detection of local residual oropharyngeal disease after chemoradiation to avoid futile routine examination under general anesthesia.

Study design: Prospective observational non-randomized multicenter study.

Study population: Fifty patients with advanced stage but resectable squamous cell.

Intervention: (DW-)MRI, 18FDG-PET-CT and (routinely performed) examinations under general anesthesia (EUA) 3 months after chemoradiation. MRI is compared with pretreatment MRI.

Main study parameters/endpoints: The primary endpoint is accuracy with which diagnostic tests reduce the number of avoided futile EUAs.
Secondary endpoints are interobserver agreement, SUV (FDG-PET) and ADC (DW-MRI) thresholds, associated costs and burden of diagnostic procedures and health related quality

of life.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In current clinical practice all these patients would already undergo imaging (MRI and/or PET) pre-treatment and 3 months after treatment. Radiation exposure due to repeated PET scanning is very low as compared to the radiation therapy of these patients. These patients may already benefit from PET and MRI due to improved diagnostic pretreatment and guidance (for eventual biopsy) during examination under general anesthesia. In the future patients may benefit from MRI and PET 3 months after chemoradiation to select reliably for examination under general anesthesia. Improved imaging may be helpful in diagnosing residual disease and avoiding futile examinations under general anesthesia.

Study objective

Current clinical practice is to perform response evaluation, i.e. examination under general anesthesia (EUA), routinely at 3 months after the end of treatment in patients who underwent chemoradiation for oropharyngeal cancer. Due the high response rates more than half of the patients are exposed to unnecessary biopsies. Biopsies in previously irradiated areas may induce complaints, e.g. pain, inflammation, wound healing problems, swallowing, dyspnea. Biopsies in previously treated areas may be false negative due to sampling errors within the residual mass. Besides aforementioned burden to the patient, such a examination under general anesthesia (EUA) requires hospital stay and operating facilities. The objective is to study the value of MRI and 18FDG-PET-CT in the detection of local residual oropharyngeal disease after chemoradiation to avoid futile routine examination under general anesthesia.

Study design

PET-CT, MRI and examination under general anesthesia three months after treatment

Intervention

PET-CT, MRI and examination under general anesthesia three months after treatment

Contacts

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Eligibility criteria

Inclusion criteria

• Oropharyngeal squamous cell carcinoma

• Initially resectable

• Scheduled for chemoradiation

• ‘Informed consent’ signed by patient

Exclusion criteria

• Age < 18 years

• Pregnancy

• Physical condition contra-indication salvage surgery

• Contra-indication for MRI

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2012
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-07-2014
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	NL4348
NTR-old	NTR4704
Other	MEC : 2011/410

Study results