Evaluation of tumor variability with MRI before and during radiotherapy treatment in patients with an orpharyngeal or oral cavity carcinoma

Published: 09-09-2010
Last updated: 04-05-2024

To evaluate anatomical changes of tumor and organs at risk with MRI before and during radiation treatment.

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

Summary

ID

NL-OMON41260

Source
ToetsingOnline

Brief title
Repeat MRI study before and during radiotherapy

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
oropharyngeal/oral cavity cancer, throat cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anatomical changes, Head and neck cancer, MRI, Radiotherapy

Outcome measures

Primary outcome

Analyses:

Rigid match of MRI and CT/CBCT:

- Drawing of GTV volume on MRI and CT

- Mapping of marker position on CT and daily CBCTs

- Evaluation of volume changes preRT MRI compared to MRI in week 3

- Evaluation of marker position compared to MRI volume

- Evaluation of daily marker position on CBCT

- Comparing of organs at risk on CT, CBCT and MRI

- Evaluation of interobserver variation of three delineators

- Analysis of dosimetric consequences of volume changes during radiotherapy

- Analysis of Ktrans en Vp of the 3 MRI scans performed before the start of

treatment

Secondary outcome

Niet van toepassing

Study description

Background summary

The tumor and organs at risk change in shape and volume during a 7 week radiation treatment (1). Our current protocol doesn`t account for these anatomical changes (2,3). Repeated imaging during treatment is possible with cone beam CT (CBCT). Soft tissue contrast of tumor and organs at risk however

is insufficient to analyse the anatomical changes. This study is developed to evaluate the possibilities with MRI to evaluatie shape and volume changes during radiotherapy. Additionally, the reproducibility of the baseline MRI is evaluated To this end MRI scans will be performed just before and after investigation under anesthesia, before start of treatment and in week 3 of the radiation treatment.

References:
1.Barker JL, Garden AS, Ang KK, et al: Quantification of volumetric and geometric changes occurring during fractionated radiotherapy for head-and-neck cancer using an integrated CT/linear accelerator system. Int J Radiat Oncol Biol Phys 2004, 59:960-970
2.Vasquez Osorio EM, Hoogeman MS, Al-Mamgani A, et al: Local anatomic changes in parotid and submandibular glands during radiotherapy for oropharynx cancer and correlation with dose, studied in detail with nonrigid registration. Int J Radiat Oncol Biol Phys 2008, 70:875-882
3.Hansen EK, Bucci MK, Quivey JM, et al: Repeat CT imaging and replanning during the course of IMRT for head-and-neck cancer. Int J Radiat Oncol Biol Phys 2006, 64:355-362

Study objective

To evaluate anatomical changes of tumor and organs at risk with MRI before and during radiation treatment.

Study design

Single centre, non-randomised, MRI repeat study during radiotherapy

Study burden and risks

Patients with large inoperable oropharyngeal and oral cavity tumors suitable for chemoradiation usually are planned for PET scan and investigation under anesthesia with marker insertion for accurate tumor delineation. Before treatment, two additional MRI scans will be performed just before investigation under anesthesia and start of treatment. Additionally, during treatment an additional MRI scan will be performed in week 3. These investigations do not have major side effects, administration of contrast through an infusion has a very small risk of contrast reaction, bleeding or infection. The additional radiation burden for the patient is negliglible compared to the intensive radiotherapy treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Histology proven squameus carcinoma of oropharynx or oral cavity
- Bulky T2-4, Nx, M0
- Planned for curative radio-chemotherapy

Exclusion criteria

Contra indication for MRI

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):	10-01-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO Date:	23-11-2012
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO Date:	20-10-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
CCMO	NL32808.031.10