

Feasibility of position averaged planning-CT for head-neck tumours

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To determine the usefulness of pa-pCTLDCT to depict the average anatomy in the head/neck area during the first week of treatment, compared to standard pCT. Secondary objectives are to determine if pa-pCTLDCT has better correlation than standard pCT...

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

Summary

ID

NL-OMON42329

Source

ToetsingOnline

Brief title

Position averaged planning-CT

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

Head and Neck cancer

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: eigen afdeling

Intervention

Keyword: averaged planning-CT, positioning variation, repeat CT

Outcome measures

Primary outcome

The main study parameter is visual interpretation of anatomical agreement between image sets. The main study endpoint is the technical feasibility of pa-pCTLDCT image sets.

Secondary outcome

Secondary parameters are the average and location-specific quantitative positional differences between image sets. The main endpoint is the technical feasibility of pa-pCTLDCT image sets.

Study description

Background summary

Curative intent fractionated (chemo)radiotherapy for head-neck tumours is delivered with very high spatial accuracy, with patients positioned in a personalized rigid mask during all imaging and treatment. However, despite this mask changes in the location of tissues can occur. This includes setup variations between separate positionings, and incidental motion such as flexing of the neck, swallowing, and coughing in treatment position. Because the planning CT (pCT) that is used for target delineation is prone to these issues, it may not optimally represent the average location of tissues during treatment. Furthermore, discrepancies between the location of tissues on pCT and other imaging (such as PET) may cause confusion in multimodal target definition. These geometrical uncertainties can lead to suboptimal target definition and dose delivery, and are currently compensated by a uniform PTV expansion of 3 mm in all directions.

Van Kranen et al. recently demonstrated the concept of cone beam CT (CBCT) based position averaged planning CT using non-rigid deformation maps from consecutive CBCT scans that were acquired during the first fractions of radiotherapy (pa-pCTCBCT). The pa-pCTCBCT was able to represent the average

anatomical position of tissues during treatment, it revealed systematic deviations of standard pCT relative to the averaged anatomy of 2.5mm for bony structures and 3.4 mm for soft tissues, and re-planning of treatments based on pa-pCTCBCT resulted in lower systematic deviations. However, this approach is only applicable to re-planning during an ongoing treatment and it cannot contribute to the initial phase of (multimodal) target definition. We propose to apply lowdose CT (LDCT) based position averaging to the planning CT (pa-pCTLDCT), to achieve better representative target definition with less risk on systematic errors in treatment delivery, to provide easier correlation with PET, and to test the potential for patient- and location specific PTV margins.

Study objective

To determine the usefulness of pa-pCTLDCT to depict the average anatomy in the head/neck area during the first week of treatment, compared to standard pCT.

Secondary objectives are to determine if pa-pCTLDCT has better correlation than standard pCT with the location of metabolic lesions on FDG PET, and to determine the technical feasibility of deforming PET+LDCT to pa-pCTLDCT and of deriving patient-specific and location-specific anatomical variations from pa-pCTLDCT.

Study design

Monocenter prospective observational pilot study

Study burden and risks

No significant side effects are expected. Five additional LDCTs of the head-neck area will give an additional radiation burden of $5 \times 2 \text{ mSv} = 10 \text{ mSv}$, this is in the range of standard diagnostic procedures and is not considered a relevant risk for these patients with cancer who will receive high dose external beam radiotherapy. Patients will spend an additional 30 minutes in the hospital on the day of pCT imaging to receive the additional LDCTs (performed in the same session). Other diagnostic procedures and treatment will not be changed or delayed by participation in this study.

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

- Proven SCC of the oral cavity, oropharynx, hypopharynx or larynx
- Stage T1-4 N0-3 M0
- Scheduled for radiotherapy, with or without concurrent chemotherapy
- FDG PET/CT in treatment position planned or performed < 3 weeks before start RT
- Written informed consent

Exclusion criteria

- Age < 18 years
- Pregnant women
- Inability to provide informed consent

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): 01-12-2015

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 21-10-2015

Application type: First submission

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

CCMO

ID

NL53812.031.15