PET-CT lymphoscintigraphy for sentinel node detection in head and neck cancer: a feasibility study

Published: 01-11-2011
Last updated: 28-04-2024

Evaluation of the feasibility of sentinel node detection by PET-CT lymphoscintigraphy

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON39155

Source
ToetsingOnline

Brief title
PET-SN

Condition

- Metastases

Synonym
head and neck cancer, head and neck squamous cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: CCA-VICI

Intervention

Keyword: head and neck cancer, lymphoscintigraphy, PET-CT, sentinel node

Outcome measures

Primary outcome

identification rate of sentinel nodes as depicted by PET-CT compared to

conventional planar lymphoscintigraphy. (PART A)

Evaluation of intraoperative detection of 89Zr-Nanocoll containing lymph nodes

using a PET-probe. (PART B)

Secondary outcome

-number and localisation of sentinel nodes on both imaging modalities (PET-CT

and conventional)

-additional value of PET-CT

-evaluation of PET-probe guided detection and resection of sentinel nodes

Study description

Background summary

De sentinel node procedure appeared to be less reliable for tumors located in the floor of mouth, compared to other sites in the oral cavity.
This is probably due to the short distance between the primary tumor and the first draining lymph node(s), the sentinel node(s).
Current detection techniques (gamma camera or SPECT-CT) have a limited resolution to detect these lymph nodes.
PET-CT has a better spatial resolution and can make dynamic images as well. The latter allows for better differentiation between first and second echelon lymph nodes, resulting in less sentinel nodes that should be harvested.
The improved resolution should be able to detect sentinel nodes in the close proximity of the primary tumor.
Therefore, sentinel node detection using PET-CT may improve current procedure in selected cases.

Study objective

Evaluation of the feasibility of sentinel node detection by PET-CT lymphoscintigraphy

Study design

Feasibility, monocenter study. PET-CT lymphoscintigraphic results will be compared with conventional lymphoscintigraphic results (gamma camera or SPECT-CT).

In the first part (part A), 5 patients will be asked to participate, and they will receive an injection with the study drug 89Zr-Nanocoll, followed by PET-CT imaging directly after injection and 24 hours later. One week later, they will undergo the standard sentinel node procedure using 99mTc-Nanocoll and SPECT-CT. Imaging results of both imaging modalities (PET-CT and SPECT-CT) will be compared. If results are positive, an additional patient cohort of 5 patients (part B) will be asked to undergo the whole sentinel node procedure using the novel 89Zr-Nanocoll. These patients will be patients who have N1 disease of the neck or for which a neck dissection will be performed for reconstructive purposes, besides resection of the primary tumor. In these patients the use of 89Zr-Nanocoll will be validated, and the results of the procedure do not influence the standard treatment of the patient. Intraoperative detection of 89Zr-nanocoll containing lymph nodes will be evaluated.

Study burden and risks

PET-CT provides a better spatial resolution and anatomical information can be obtained at the same time which theoretically may show additional SN(s) that may not be seen on planar lymphoscintigraphy. Furthermore, based on the improved knowledge about the localization of the SN(s), exploration of the neck in order to find the SN may be minimized. This should results in less scar formation and tissue damage, factors that would hamper an eventual subsequent neck dissection. The CT component of PET-CT and the addition of low dose of 5 MBq 89Zr, will result in an acceptable radiation burden to the patient, i.e comparable to natural background level. No significant interference of the addition of 89Zr during the standard sentinel node is anticipated.
In PART B of the study the patients will undergo one additional PET-CT scan after administration of 5 MBq 89Zr-Nanocoll one day prior to surgery. The results of the SN procedure will not influence standard treatment. From a patient perspective the advantage of this study might be the visualisation of unexpected drainage outside the surgical field, which can be discussed with the patient, possibly leading to a better individualized treatment.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Early stage oral cavity carcinoma (T1-2, cN0) scheduled for transoral excision and sentinel node procedure (Part A)
* Oral cavity carcinoma (maximum tumor size 4 cm) which are scheduled for more extensive surgery including neck dissection, e.g. for patients with proven lymph node metastases (max. N1 disease) or patients in which the primary tumor cannot be resected transorally and for which the neck is opened for reconstruction purposes (Part B)
* Age>18 years
* Previously untreated
* Written informed consent

Exclusion criteria

1. presence of nodal disease in the neck (PART A);2. prior treated by radiotherapy, chemotherapy, or surgery in the head and neck area;3. pregnancy

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):	18-04-2012
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	89Zr-Nanocoll
Generic name:	89Zr-Nanocoll

Ethics review

Approved WMO Date:	01-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2011

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2011-002711-29-NL
CCMO	NL37222.029.11