Sentinel lymph node detection of cervical occult lymph node metastases in patients with parotid gland carcinoma by means of sentinel node biopsy using 68-galium-tilmanocept PET-CT.

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This study has been transitioned to CTIS with ID 2024-514233-37-00 check the CTIS register for the current data. To evaluate the feasibility and prove the concept of sentinel node biopsy in patients with carcinoma of the parotid gland and scheduled...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Head and neck therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON51066

Source
ToetsingOnline

Brief title
SNParotid

Condition

- Head and neck therapeutic procedures

Synonym
Parotid carcinoma, salivary gland tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lymph node metastases, Parotid carcinoma, Sentinel node

Outcome measures

Primary outcome

The primary endpoint of this study is the feasibility of the sentinel node biopsy procedure in patients with carcinoma of the parotid gland with N0 neck scheduled for parotidectomy with elective neck dissection, using preoperative 68-galium-tilmanocept PET/CT combined with intraoperative gamma probe and fluorescence camera localization.

Secondary outcome

• To compare histopathologic results (presence or absence of isolated tumor cells and (micro-)metastasis) of the excised sentinel lymph node(s), and elective neck dissection specimens.

• To investigate in which levels the sentinel lymph nodes are localized and the number of sentinel lymph nodes.

• To investigate the best timing of PET/CT.

• The incidence and degree of postoperative complications, graded by means of the Clavien-Dindo classification of Surgical Complications.

Study description

Background summary

In patients with carcinoma of the parotid gland the management of the clinically negative neck is a controversial issue. In most patients a selective (L I-III) neck dissection is performed wit associated morbidity. However, a substantial number of these elective neck dissections are futile. The current diagnostic techniques are not accurate enough to detect occult lymph node metastases. The sentinel node procedure may be useful to acurately select patients for neck dissection. So, overtreatment of the clinically negative neck will be reduced in the future, as only the patients with positive sentinel lymph node(s) will be eligible for elective neck node dissection.

Study objective

This study has been transitioned to CTIS with ID 2024-514233-37-00 check the CTIS register for the current data.

To evaluate the feasibility and prove the concept of sentinel node biopsy in patients with carcinoma of the parotid gland and scheduled for parotidectomy and elective neck dissection.

Study design

The proposed study is an observational, non-randomized feasibility study and will be conducted at UMC Utrecht.

Study burden and risks

Sentinel node biopsy is a procedure which is used routinely in other head and neck carcinomas. In the literature on head and neck cancer no serious adverse events have been reported using these techniques. Sentinel node biopsy will be performed by experienced head and neck surgeons during surgery of the primary tumor. Neck dissection in combination with sentinel node biopsy stages the neck more accurately (by detecting micrometastases and single tumor cells which may be missed during routine examination of lymph nodes) than neck dissection alone. Findings from this feasibility study may have implications for future treatment planning.

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

1. The patient has provided written informed consent authorization before participating in the study.
2. The patient has a diagnosis of primary carcinoma of the parotid gland, and is stage T1-T4, cN0, M0 (see Appendix 3: TNM staging AJCC UICC 8th edition).
3. Clinical nodal staging (cN0) has been confirmed by negative results from CT, MRI, PET/CT and/or ultrasound-guided fine needle aspiration cytology within 30 days of the SLNB procedure.
4. The patient is a candidate for parotidectomy and elective (selective or modified radical) neck dissection.
5. The patient is >=18 years of age at the time of consent.
6. The patient has an ECOG status of Grade 0 - 2 (see Appendix 4: ECOG Performance Status Grading).

Exclusion criteria

1. The patient is incapacitated.
2. The patient has had a previous allergic reaction after administration of a radionuclide tracer.
3. The patient has clinical or radiological evidence of metastatic cancer to the regional lymph nodes.

4. The patient has a history of neck dissection, or gross injury to the neck that would preclude reasonable surgical dissection for this trial, or radiotherapy to the neck.
5. The patient is actively receiving systemic cytotoxic chemotherapy.
6. The patient is on immunosuppressive, anti-monocyte, or immunomodulatory therapy.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Not applicable
Generic name:	68-galium-tilmanocept
Product type:	Medicine
Brand name:	Not applicable
Generic name:	ICG-99m-technetium-nanocolloid

Ethics review

Approved WMO

Date:	23-09-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-09-2021
Application type:	First submission
Review commission:	METC NedMec

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
EU-CTR	CTIS2024-514233-37-00
EudraCT	EUCTR2021-003068-28-NL
CCMO	NL77946.041.21