Validation of ICG-99mTc-nanoscan as hybrid tracer for sentinel node biopsy

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This study has been transitioned to CTIS with ID 2024-519351-28-00 check the CTIS register for the current data. Cross validation of the hybrid tracer ICG 99 Tc Nanoscan with respect to 99m Tc Nanoscan for the determination. In particular the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON51806

Source
ToetsingOnline

Brief title
NANOSCAN

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
head/neck/trunk melanoma, oral malignancies, penile carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: 99mTc-Nanoscan, ICG-99mTc-nanoscan, preoperative lymphoscintigraphy imaging, Sentinel node biopsie

Outcome measures

Primary outcome

1. To show concordance between ICG-99mTc-Nanoscan and 99mTc-Nanoscan SLN visualized on preoperative lymphoscintigraphy and SPECT/CT imaging, where concordance is defined as at most 1 sentinel node detected by one tracer being missed by the other tracer.

Secondary outcome

1. Number of higher-echelon nodes visualized on preoperative lymphoscintigraphy and SPECT/CT imaging for both tracers (ICG-99mTc-Nanoscan and 99mTc-Nanoscan);

2. Concordance between intraoperative fluorescence and radioactive findings using:

• Number and intensity of the fluorescent nodes at time of excision;

• Number and radioactive signal intensity of the radioactive nodes at time of excision;

Study description

Background summary

The Sentinel node procedure has been successfully used for decades for the adequate staging of solid tumors (e.g. head and neck, urological, gynecological tumors as well as melanoma and breast cancer). This procedure is used in clinically node negative (cN0) patients. For the SN procedure, a radiotracer is used, which travels to the first node(s) on which a tumor drains, the SN. Using

lymphoscintigraphy, preoperative mapping of the SN is done. In Europe 99m Tc Nanocoll is considered the standard for sentinel node biopsy.

As a response to the surgical needs, the SN approach has been enriched with fluorescence through a collaboration between AvL and LUMC, resulting in the hybrid tracer indocyanine green (ICG)-99mTc-Nanocoll. This hybrid tracer not only emits gamma rays but also fluorescence light. This ensures that the surgeon receives real-time acoustic as well as visual input on the localization of the SN. Before this tracer was been incorporated to use in daily practice, the study of Brouwer et al (NL26699.031.09 N09DRF) showed that the behavior of the hybrid tracer is identical to the golden standard by using preoperative lymphoscintigraphy. Since then, the SN procedure in head and neck and penile cancer have been routinely performed with the hybrid tracer Indocyanine Green (ICG)-99m Tc Nanocoll. After initial in-house production (AvL and LUMC), this tracer was commercially provided by the radiopharmacy of GE healthcare for years.

Recently, the raw material Nanocoll is no longer available. 99mTc-Nanocoll has been replaced by 99mTc-Nanoscan. Chemically, Nanoscan is identical to Nanocolloid; it concerns both an albumin aggregate (nanocolloid) of a similar size. The product formulation, however, differs slightly. Despite the same pharmaceutical specificity and product characteristics, the imaging of both preparations may differ in details. Something that may impact on the formation of a hybrid tracer analogue. his is important for the creation of the hybrid analogue ICG-99mTc-Nanoscan. Nanocoll has not been available since May of this year, with the hybrid tracer Indocyanine Green (ICG)-99mTc-Nanocoll also replaced by the analogue nanoscan; Indocyanine Green (ICG)-99mTc-Nanoscan. Since this replacement, there are already 8 centers that purchase this hybrid form from the usual supplier, GE Healthcare, for use in routine patient care.

In the past, we have demonstrated that such comparison scan be performed in a relatively small group of patients whereby the patient acts as its own control. At first, we used this concept for 99m Tc Nanocoll and ICG 99m Tc Nanocoll (L26699.031.09 N09DRF) and from this emerged that both tracers revealed a comparable SN visualization but the last option allowed for additional intra operative fluorescence imaging. Later on, we used the set up to compare ICG 99m Tc Nanocol l and 99m Tc SentiScint (NL45185.031.13N13ICG) was performed which showed that changing the particle size impacted the lymphatic flow but had no influence on the SN visualization overall.

As no comparison study has been done with the "new" hybrid tracer (ICG)-99mTc-Nanoscan, we would like to perform a validation of the SN procedure with ICG-99mTc-Nanoscan. We want to set up this study in analogy with the comparison study we conducted before the introduction of ICG-99mTc-Nanocolloid (99mTc-Nanocoll vs. ICG-99mTc-Nanocoll (NL26699.031.09 - N09DRF). In particular, we want to validate that the hybrid ICG-99m Tc-Nanoscan shows the same preoperative gland involvement on preoperative lymphoscintigraphy and that

the intraoperative signal intensities remain the same. All this to maintain the level of current care.

Study objective

This study has been transitioned to CTIS with ID 2024-519351-28-00 check the CTIS register for the current data.

Cross validation of the hybrid tracer ICG 99 Tc Nanoscan with respect to 99m Tc Nanoscan for the determination. In particular the intraoperative fluorescence detection and scintillation detection will be validated for ICG 99 Tc Nanoscan. In addition, the preoperative lymphoscintigraphic outcome of ICG 99 Tc Nanoscan will compared to that of the 99m Tc Nanoscan, with patient being his own control. The validation will be done in 29 patients with melanoma of the head and neck area or upper part of the trunk, oral malignancies or penile carcinomas who are scheduled for sentinel node biopsy.

Study design

Prospective drug-induced study.

Study burden and risks

Instead of once, patients are requested to visit the department of Nuclear Medicine twice. For this study, the patient will receive one additional injection with ICG-99mTc-Nanoscan. This means that patients will receive one additional dose of four injections with radioactivity. In addition, one additional SPECT/CT will be acquired. The total dose of radioactivity is within the limits that are indicated by the Gezondheidsraad, in the *Normen voor de toediening van radioactieve stoffen aan vrijwilligers*.

Rarely, nausea, urticaria and anaphylactic reactions (<1/ have been reported after intravenous injection of 5 25mg ICG. Because of the proposed exclusion criteria and the intracutaneous injection, these numbers may be assumed to be lower within this study. In rare case side effects like nausea, urticaria and anaphylactic reactions are reported with the use of Nanocoll. Up until now, there has been no reports of these side effects using ICG 99m Tc N anocoll (N>1500 patients) and because we do not change the amount of ICG (250 mg) we don*t expect this to happen.

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

* Patient who will undergo a sentinel node procedure in routine care.
* Patients > 18 years;
* Patients presenting with a primary cutaneous melanoma of head/neck, upper part of the trunk, and extremities;
* Patients presenting with a primary oral cavity malignancyT1-2N0;
* Patients with primary penile cancer;
* Patients with clinical N0 stage;
* Patients scheduled for a sentinel node biopsy prior to (re-)excision of the primary lesion;
* Patients in which ICG-99mTc-nanoscan would be used in routine care or a research setting

Exclusion criteria

* Patients with known allergy to patent blue dye;
* Patients who are pregnant or breast-feeding mothers;
* History of hypersensitivity reactions to products containing human serum

albumin;
* History of iodine allergy
* Hyperthyroid or thyroidal adenoma
* Kidney insufficiency
* Incapacity or unwillingness of participant to give written informed consent;

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-11-2023
Enrollment:	29
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ICG-99mTc-Nanoscan
Generic name:	ICG-Tc-nanoscan

Ethics review

Approved WMO

Date:	27-12-2022
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	24-01-2023
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	CTIS2024-519351-28-00
EudraCT	EUCTR2022-003297-24-NL
CCMO	NL79884.041.22