Within-patient comparison of Senti-Scint and ICG-99mTc-nanocolloid for sentinel node biopsy of melanoma of the head and neck, of the trunk or of an extremity

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To compare ICG-99Tc-nanocolloid to 99mTc-Senti-Scint for sentinel node mapping in patients with malignant melanoma of the trunk, an extremity or in the head and neck area.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40198

Source
ToetsingOnline

Brief title
99mTc-Senti-Scintvs. ICG-99mTc-nanocolloid

Condition

- Skin neoplasms malignant and unspecified
- Skin and subcutaneous tissue therapeutic procedures

Synonym
cutaneous melanoma, Melanoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lymph node metastasis, Melanoma, Sentinel node biopsy

Outcome measures

Primary outcome

1) Number of higher-echelon nodes following lymphoscintigraphy and SPECT/CT

imaging with either approach.

Secondary outcome

1) Number of draining basins and sentinel nodes visualized with

lymphoscintigraphy and SPECT/CT following 99mTc-Senti-Scint administration and

after ICG-99mTc-nanocolloid administration.

Study description

Background summary

Sentinel node biopsy is routinely used for staging melanoma patients., The sentinel node procedure is conventionally performed after injecting a radiocolloid around the tumor site. In the head, neck and extremities, drainage is fast and subsequent nodes are often depicted on the lymphoscintigrams in addition to the sentinel node(s). This may complicate both the interpretation of the images and the surgical procedure. The occurrence of higher-echelon nodes is less frequent on the trunk but in this area aberrant drainage is more often seen. Better visualization of lymphatic vessels running to these sentinel nodes would be advantageous.
The number of visualized nodes depends on the size of radiocolloid particles and the time between injection and imaging. The larger the radiocolloid particles, the slower the drainage. The longer the time interval between injection and imaging, the greater the number of visualized nodes. 99mTc-nanocolloid-ICG) is the traditional radiocolloid in Europe. Recently, 99mTc-Senti-Scint was introduced for sentinel node biopsy. The latter consists of large particles (100-600nm) and as such it is claimed to have a lower rate of visualisation of second-tier nodes. Aew studies reported on the use of

99mTc-Senti-Scint, but no comparative studies have been performed yet.

Study objective

To compare ICG-99Tc-nanocolloid to 99mTc-Senti-Scint for sentinel node mapping in patients with malignant melanoma of the trunk, an extremity or in the head and neck area.

Study design

It is a prospective interventional study.

Intervention

The study will be performed in a two-day protocol.
Day 1: The four sites for the radiocolloid injection deposits will be marked with an indelible marker pen. Thereafter, 99mTc-Senti-Scint will be administered intracutaneously around the lesion site and the 4 injections locations will be marked on skin. Dynamic lymphoscintigraphy will be performed immediately after injection followed by static lymphoscintigraphy at 15 minutes and 2 hours. After 2 hours, SPECT/CT imaging will be performed.
Day 2: Prior to injection of ICG-99mTc-nanocolloid a static posterior or anterior lymphoscintigram will be made (roughly 18 hours after the first injection). ICG-99mTc-nanocolloid will be injected intracutaneously around the lesion site at the locations marked on day 1. Similar to day 1, dynamic and static lymphoscintigraphy will be performed followed by SPECT/CT imaging. The operation will be performed on the afternoon of the second day. The operation will be performed according to standard protocol. Sentinel nodes will be examined by the pathologist in the standard fashion.

Study burden and risks

Instead of once, patients have to come to the hospital twice to receive an additional tracer injection. This means that patients will also receive twice the radioactivity dose. The additional radioactivity is comparable to other standard nuclear medicine procedures. The use of 99mTc-Senti-Scint for lymphatic mapping in colorectal cancer has been approved by the local ethics committee of the NKI-AVL. The total dose of radioactivity lies within the limits that are indicated by the Gezondheidsraad, in the *Normen voor de toediening van radioactieve stoffen aan vrijwilligers*.
Rarely, nausea, urticarial and anaphylactic reactions (ICG: <1/10000) have been reported after intravenous injection. Because of the proposed exclusion criteria and the local, intracutaneous, injection, these numbers will be lower within this study.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2300RC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients > 18 years;- Patients with a primary melanoma of the head and neck (including skull);- Patients with a primary melanoma on the trunk;- Patients with a primary melanoma of an extremity;- Patients have a clinically node negative (cN0) regional lymph node status;- Patients are scheduled for (re-)excision of the melanoma (scar) and a subsequent sentinel node biopsy procedure

Exclusion criteria

- Patients with a known allergy to patent blue;- Patients who are pregnant or nursing mothers;- Patients with a history of hypersensitivity reactions to products containing human serum albumin;- Patients with a history of an iodine allergy;- Patients with a hyperthyroid or

thyroidal adenoma;- Patients with known kidney insufficiency

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-10-2014
Enrollment:	38
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-04-2014
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
EudraCT	EUCTR2013-005397-22-NL
CCMO	NL45185.031.13