Gebruik van 99mTc-Senti-Scint in vergelijking met ICG-99mTc-nanocolloid voor de schildwachtklierprocedure bij melanomen

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27024

Source
Nationaal Trial Register

Brief title
Senti-Scint vs. ICG-nanocolloid for melanoma SN biopsy

Health condition

melanoma of the head and neck, melanoma of the trunk, melanoma of an extremity, sentinel node biopsy

Sponsors and support

Primary sponsor: NKI-AVL
Source(s) of monetary or material Support: NKI-AVL, NWO-STW-VIDI, ERC-starting grant

Intervention

Outcome measures

Primary outcome

1. Number of draining basins and sentinel nodes visualized with lymphoscintigraphy and SPECT/CT imaging;

2. Number of higher-echelon nodes visualized with lymphoscintigraphy and SPECT/CT imaging;

3. Number of visualized sentinel nodes with a clear lymphatic vessel running from the injection site to the sentinel node.
The parameters mentioned will be studied for both ICG-99mTc-nanocolloid and 99mTc-Senti-Scint.

Secondary outcome

1. Number of fluorescent and radioactive nodes at the time of excision;

2. Number of radioactive nodes only at the time of excision;

3. Number of fluorescent, radioactive and blue nodes at the time of excision;

4. Number of radioactive and blue nodes at the time of excision;

5. Histopathological examination results of the excised sentinel nodes.

Study description

Background summary

Sentinel node biopsy is routinely used for staging of melanoma patients. The sentinel node procedure is traditionally performed after injecting a radiocolloid around the tumor site followed by lymphoscintigraphy and/or single photon emission computed tomography combined with computed tomography (SPECT/CT) to determine the number and (anatomical) location of the sentinel node(s). For melanoma of the head and neck, or of an extremity, drainage is fast and overflow from the sentinel nodes to higher-echelon node(s) frequently occurs, which can complicate distinguishing these two from each other. 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 as such allowing discrimination of the sentinel nodes and higher-echelon nodes, but also allows identification of aberrant drainage patterns.
The number of visualized nodes depends on the size of the radiocolloid particles used and the time between injection and imaging. The longer the time interval between injection and imaging, the higher the number of visualized nodes and as such visualization of higher-echelon nodes.
Traditionally in Europe, (indocyanine green (ICG)-)99mTc-nanocolloid (20-100 nm) is used for sentinel node biopsy. Recently, 99mTc-Senti-Scint was introduced for this purpose. The latter

consists of larger particles (100-600 nm) and as such it is claimed to have a lower rate of visualization of higher-echelon nodes due to its slower movement. Only few studies reported on the use of 99mTc-Senti-Scint, but no comparison studies with 99mTc-nanocolloid have been performed yet.

Study objective

Analysis of the lymphatic drainage pattern using 99mTc-Senti-Scint identifies the same SNs, but fewer higher-echelon nodes, as when ICG-99mTc-nanocolloid is used.

Study design

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Intervention

Day 1:

Surrounding the melanoma (scar) the 4 sites for the radiocolloid injection deposits will be marked with an indelible marker pen. Thereafter, 0.4 mL of 90MBq (±10%) 99mTc-Senti-Scint will be administered intracutaneously around the primary lesion site at the 4 marked locations (0.1. mL per deposit). Dynamic (anterior or posterior and lateral) lymphoscintigraphy will be performed immediately after injection followed by static (anterior and lateral) lymphoscintigraphy at 15 minutes and 2 hour after injection. After 2 hours SPECT/CT imaging will be performed.

Day 2:

Prior to injection of ICG-99mTc-nanocolloid a static anterior lymphoscintigram will be made (roughly 18 hours after the first injection). A dose of 0.4 mL of 90 MBq (±10%) ICG-99mTc-nanocolloid will be injected intracutaneously at the locations marked on day one (0.1 mL per depot). Similar to day 1, dynamic and static lymphoscintigraphy will be performed followed by SPECT/CT imaging.

The operation will be performed of the afternoon of day 2. Sentinel node(s) and re-excision of the melanoma scar will be performed.

Contacts

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Eligibility criteria

Inclusion criteria

• Patients >18 years;

• Patients with a primary melanoma of the trunk , of an extremity or in the head and neck region;

• Patients with a clinically node negative (N0) regional lymph node status;

• Patients are scheduled for (re-)excision of the melanoma (scar) with a sentinel node biopsy.

Exclusion criteria

• Patients with known allergy to patent blue;

• Patients who are pregnant or nursing mothers;

• History of hypersensitivity reactions to products containing human serum albumin;

• History of iodine allergy;

• Hyperthyroid or thyroidal adenoma;

• Kidney insufficiency.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-08-2014
Enrollment:	38
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-08-2014
Application type:	First submission

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
NTR-new	NL4568
NTR-old	NTR4736
Other	NL45185.031.13 : N13ICG

Study results

Summary results

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