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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27024

Bron
Nationaal Trial Register

Verkorte titel
Senti-Scint vs. ICG-nanocolloid for melanoma SN biopsy

Aandoening

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

Ondersteuning

Primaire sponsor: NKI-AVL
Overige ondersteuning: NKI-AVL, NWO-STW-VIDI, ERC-starting grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-08-2014
Aantal proefpersonen:	38
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4568
NTR-old	NTR4736
Ander register	NL45185.031.13 : N13ICG

Resultaten

Samenvatting resultaten

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