Near-infrared fluorescence imaging using indocyanine green as an adjunct to improve standard-of-care sentinel lymph node procedure in pediatric patients with melanoma or sarcoma of head/neck/trunk, paratesticular or extremities: a feasibility trial

Published: 15-04-2020
Last updated: 08-04-2024

To determine the feasibility of using ICG to optically guide the surgeon to the SLN of paediatric melanoma and sarcoma patients. The SNP is a diagnostic procedure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON52846

Source
ToetsingOnline

Brief title
ICG to improve sentinel lymph node procedure in pediatric patients

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Therapeutic procedures and supportive care NEC

Synonym

lymph node, sentinel node

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fluorescence guided surgery, indocyanine green, pediatric oncology, sentinel node procedure

Outcome measures

Primary outcome

The intraoperative detection of SLNs in paediatric patients who received a

pre-operative injection of ICG-99mTc-nanocolloid without blue dye. This is

called detection rate, which is the percentage of patients in which the SLN is

detected using ICG.

Secondary outcome

1. Evaluation of NIR fluorescence for the SLN procedure by the surgeon by means

of a short questionnaire;

2. Correlation between NIR fluorescent and radioactive SLNs;

3. Number of failures to find the preoperatively detected SLN;

4. Tumor to background ratio;

5. The safety of using a pre-operative injection of ICG-99mTc-nanocolloid for

the SLN procedure in paediatric patients.

Study description

Background summary

The standard-of-care sentinel lymph node (SLN) procedure in paediatric cancer patients consists of a preoperative intradermal injection with 99mTechnetium-nanocolloid as radiotracer in combination with an intraoperative injection of blue dye for optical guidance. This method has been proven to accurately detect the SLN in paediatric melanoma and sarcoma patients with a detection rate of around 95% nowadays. To localize a SLN a radiotracer such as 99mTc-nanocolloid is essential, because successful SLN identification depends on the radioactive signal detected by a handheld gamma probe. However, disadvantages of using a radiotracer are the disturbance of the radioactive signal originating from the injection site, a low spatial resolution and the fact that the surgery has to be interrupted in order to use the gamma probe. Consequently, it is sometimes difficult to find the true SLN. These limitations of the radiotracer can be abolished by using at the same time an agent that could aid optical guidance and does not interrupt the surgery. Therefore, if deemed necessary, blue dye is currently used to optically support the surgeon during the SLN procedure. However, the use of blue dye has evident disadvantages such as risk of severe allergic reactions and long lasting tattooing, in addition to the limited penetration depth and alteration of the surgical field. Furthermore, the efficacy is low with only 60% of SLNs staining blue.
In adult melanoma patients, near-infrared (NIR) fluorescence imaging using indocyanine green (ICG) has been shown to be a safe, efficient and accurate method for intra-operative visual identification of SLNs, with a higher sensitivity (up to 97%) compared to blue dye. Furthermore, good safety profiles are also established for the paediatric population, although for other indications. Due to the high performance of ICG in adults and the good safety and favourable side-effects profile of ICG compared to blue dye, we expect that a combined intradermal injection of ICG noncovalently bound to 99mTc-nanocolloid (ICG-99mTc-nanocolloid) is able to retain or even improve the optical guidance during surgery, while preventing the considerable risk of side-effects when using blue dye.

Study objective

To determine the feasibility of using ICG to optically guide the surgeon to the SLN of paediatric melanoma and sarcoma patients. The SNP is a diagnostic procedure.

Study design

A feasibility single-institution trial to assess the use of ICG combined with 99mTc-nanocolloid for the SLN procedure of paediatric patients with melanoma or sarcoma of the extremity, paratesticular, head, neck or trunk. Standard-of-care SLN procedure will be performed (99mTc-nanocolloid). ICG will be premixed with

99mTc-nanocolloid prior to injection (two separate agents). In accordance with the standard-of-care SLN procedure, blue dye will be used in addition if deemed necessary by the surgeon.

Study burden and risks

Using ICG in adjunct to the already used 99mTc-nanocolloid does not give any extra burden for the patients, since no extra visits, physical examinations or other tests, questionnaires or diaries, injections or blood samples are needed. In addition, no significant risks were identified by our institutional prospective risk analysis other than a very small risk (<1:10.000) of an allergic reaction to ICG. In order to minimize this risk, patients with an allergy for iodine and those with a renal insufficiency are excluded from this study. Because of the favourable side-effect profile in addition to the increased SLN identification of ICG compared to blue dye, ICG is currently used as standard-of-care in many hospitals treating adult patients, showing the evident potential benefit for paediatric patients. Furthermore, although the use of the Quest NIR camera for this indication is outside its intended use, we do not expect any additional risk, because the visualization method is similar to tissue perfusion: its intended use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

Pediatric patients with melanoma or sarcoma of head/neck/trunk, paratesticular or extremities that have an indication for a sentinel node procedure.
Age 0-18 years.
Written informed consent from patient/parents/legal guardians, according to local law and regulations.

Exclusion criteria

1. Allergy to iodine
2 Hypersensitivity to ICG
3. Kidney insufficiency (eGFR<55)
4. Clinical manifest hyperthyroidism/ autonomous thyroid adenoma
5. Nanocolloid or shell fish allergy (same as in standard care: or Technetium-nanocolloid use)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2020

Enrollment:	22
Type:	Actual

Medical products/devices used

Generic name:	Quest Spectrum camera and Vesira Elite II
Registration:	Yes - CE outside intended use
Product type:	Medicine
Brand name:	Indocyanine Green (ICG)
Generic name:	Indocyanine Green (ICG)
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-04-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-05-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-11-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-03-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-04-2022

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-08-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-09-2022
Application type:	Amendment
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	EUCTR2020-000509-96-NL
CCMO	NL71166.041.20
Other	NTR NL7935