Pilot study on the validation of fluorescence imaging of lymph nodes during colorectal lymphadenectomy, using indocyanine green.

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Feasibility study: The potential use of intraoperative, ICG based, fluorescence imaging of LN*s during CRC lymphadenectomy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32756

Source
ToetsingOnline

Brief title
Intraoperative lymphatic mapping using ICG in colorectal carcinoma.

Condition

- Other condition
- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
colon and/or rectum cancer, colorectal carcinoma

Health condition

lymfatische metastasering

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colorectal carcinoma, Fluorescence imaging, Indocyanine green, Lymphadenectomy

Outcome measures

Primary outcome

Theoretically the following primary goal should be achieved, using ICG:

In at least 65% of the resected LN*s should become visible with fluorescence

Secondary outcome

Theoretically the following secundary goal should be achieved, using ICG:

Fluorescence identification of the SLN in at least 80% of the cases

Study description

Background summary

Adjuvant systemic chemotherapy is indicated in colorectal carcinoma (CRC) patients with metastatic lymph nodes (LN's), resulting in a 30% relative increase in survival.
To assess the actual LN status optimal examination by means of adequate LN dissection is mandatory. The Dutch CRC treatment guidelines require a minimum of 10 LN*s to be examined for adequate staging. However, it has recently been demonstrated that often a median number of 6 LN*s are examined among CRC patients in the Netherlands. This may be due to the difficulty of intraoperative detection of these LN*s, demanding a technique that enables the surgeon for more accurate identification of LN*s during the surgical procedure. In addition, the intraoperative detection of the sentinel lymph node will allow the pathologist to examine in more detail the possibility of metastasis.
Where other carcinomas such as breast cancer, have well established techniques

to guide SLN surgery, no such technique is yet available for CRC.
Recent studies suggest that a new procedure, using an FDA approved, fluorescent (indocynanine green; ICG), could allow for highly sensitive detection of the lymphatic outflow track and draining LN*s. Therefore, ICG is expected to improve lymphatic mapping, SLN detection and subsequent lymphadenectomy. Consequently, staging of CRC and postoperative outcome will improve.

Study objective

Feasibility study: The potential use of intraoperative, ICG based, fluorescence imaging of LN*s during CRC lymphadenectomy.

Study design

No special patient preparation is required. During surgery 4 ml of ICG solution (25 mg) will be injected in/around the tumor (similar to standard patent blue procedure in breast cancer). Dynamic imaging by a dedicated camera during 15 min post injection will help detect the lymphatic outflow track with visualization of the majority of draining lymph nodes, including the first draining lymph node (sentinel node). Subsequently, all the fluorescent LN*s will be resected and marked for PA.

Study burden and risks

Other than intraoperative injection and tracking of ICG, this study will not be any different of standard procedures. During the ICG-injection the patient will be anesthetised and therefore experience no extra burden. Operating time may, however, be prolonged by 15 min. due to the imaging procedure. Conversely, the value of an improved and more adequate lymphadenectomy could have a major impact in the improvement of staging and postoperative outcome in CRC patients. In rare cases (< 1/10.000) nausea, urticaria and anaphylactic reactions have been reported. Because of the proposed exclusion criteria, these numbers will in fact be lower within this study.

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

1. Histology proven CRC of the colon ascendens, transversum, descendens or sigmoid
2. Any histological grade
3. Scheduled for surgical resection
4. Age: >18 years

Exclusion criteria

1. History of allergy to iodides
2. Hyperthyroid or autonomic thyroidal adenoma
3. Kidney insufficiency
4. Pregnancy or lactation

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	ICG-Pulsion
Generic name:	Indocyanine green
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	22-07-2008
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	EUCTR2008-003955-65-NL
CCMO	NL24049.031.08