In-vivo sentinel lymph node mapping in patients with colorectal cancer

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1. To determine the feasibility of SLNM in CRC.2. To assess the accuracy of SLNM in the status of the regional nodes.3. To identify aberrant mesenteric lymphatic drainage patterns.

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON30234

Source
ToetsingOnline

Brief title
Sentinel lymph node mapping in patients with colorectal cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Colorectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Ziekenhuis zelf.

Intervention

Keyword: Carcinoma, Colon, rectum, Sentinel node

Outcome measures

Primary outcome

1. To define whether SLNM can adequately identified nodal involvement in

CRC

2. To define detection rate (upstaging) and aberrant nodal drainage.

Secondary outcome

1. To determine which factors may influence the concept of SLN, such as

tumorsize, location etc.

Study description

Background summary

The presence of lymph node metastases remains the most reliable prognostic predictor and the gold indicator for adjuvant treatment in colorectal cancer (CRC). The presence of nodal involvement decreases the 5-year survival with 25-35%. The chance of cure in patients with nodal metastases (Dukes C) is less than 50%. One third of these patients may cure by the addition of adjuvant chemotherapy. In spite of potentially curative resection, about 10% of the patients with Dukes A and 15-30% with Dukes B tumours will eventually develop recurrent disease within 5 years. In fact, 20 to 30% of CRC patients testing negative for lymph node metastasis will subsequently develop systemic metastases within 5 years. False-negative pathology for (occult) metastases may be one of the causes for this later systemic spread. Most of these N0 CRC patients harbour occult nodal or micro metastases and may therefore benefit from adjuvant treatment. 1-3
These nodal metastases are usually less than 2 mm in size and can be missed on routine examination. With sentinel lymph node biopsy (SLNB) it is currently possible to predict the nodal status in several solid tumours with a high degree of certainty.
The main advantage in CRC nowadays is to assess more accurately the true negative status of the nodal basin and to allow extensive examination on the pathologic material of one to four SLNs, such as immunohistochemistry (IHC). The biological implication of micro metastases generally referred as occult or less than 2 mm in diameter, still has to be defined. Bases on currently available non-randomised data, the significance of micro metastases is difficult to determine. Due to different techniques used among trials it is not

possible to compare studies properly or to perform a good meta-analysis of previously reported studies.
Clearly, further studies are indicated to identify whether micro metastases detected by SLNB procedure are able to predict the advantage of adjuvant treatment in CRC patients. The value of sentinel lymph node mapping (SLNM) is twofold. It will provide more intensive pathological analysis and more accurate staging and may show unusual lymphatic drainage leading to a modification of the extend of the resection.

Study objective

1. To determine the feasibility of SLNM in CRC.
2. To assess the accuracy of SLNM in the status of the regional nodes.
3. To identify aberrant mesenteric lymphatic drainage patterns.

Study design

Patent blue dye V 0.5 - 2 ml is injected in case of colon tumours subserosally around the tumour immediately after laparatomy and intra-abdominal palpation and exclusion of distant metastases. Some mobilisation of the bowel along the paracolic gutter is needed to deliver the bowel adjoining the tumour near the surface. In patients with a rectal tumour the blue dye V (0.5 - 2 ml) is injected by a rigid scope through the anus submucosal around the tumour. The mesenteric dissection should be limited to a minimum to prevent disruption of the lymphatic vessels. The first two to six blue stained nodes are marked with a suture (suture-tagged). The lymphatic vessel containing the blue dye is followed proximally to the site of the primary neoplasm to ensure that there are no SLNs hidden in the mesenteric fat. Other blue nodes may appear during resection but these should not be marked as SLNs. After all SLNs are marked, an en bloc resection is performed. SLNs are defined as the first 6 lymph nodes that localized blue dye within the regional basin. Bases on the hypothesis that the lymphatic drainage occurs in a step-wise fashion, these lymph nodes should reflect the pathological status of the regional node basin.
The pathologist examines the specimen by conventional methods and selects the blue stained nodes and put them into marked cassettes so that they can be identified by microscopic examination. All of the nodes, sentinel and non-sentinel nodes, are examined by conventional methods (H&E staining). If the sentinel node is negative or the non-sentinel node is positive and the sentinel node is negative additional staining with Cytokeratin (CK) is performed on the sentinel nodes.

Study burden and risks

Due to the blue dye the urine and stool may be discoloured over 24 to 48 hours after surgery. Transient intraoperative hypotension and tachycardia usually responding rapidly to a fluid bolus, and transient skin rash (urticaria) that

responds to diphenhydramine as a result of allergic reactions may occur. In series of over 2100 patients only 0.42% demonstrated allergic reactions manifested by an initial wheal reaction at the injection site, followed by the development of blue hives scatterd at the regional area. Generally there is a rapid response to in intravenous diphenhydramine and occasionally methyl prednisolone. Patients had to be followed for at least 60 minutes. Physicians may be hesitant to inject a substance into the tumour because of fear for causing dissemination. However, there are no known data indicating that intratumoral injections may result in a decreased survival. Patent blue dye V is registered in the Netherlands.

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

Colorectal carcinoma
Age > 18 years
No metastases
Fit for treatment

Exclusion criteria

Age < 18 years
Previous resection on the colon/ rectum
Pregnant women

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):	01-11-2006
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
CCMO	NL15193.028.06