In vivo sentinel node procedure in patients with resectable colon cancer, a pilot study.

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

Summary

ID

NL-OMON33423

Source
ToetsingOnline

Brief title
VISCO study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colon cancer, large bowel cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: financiering aangevraagd bij jandekkerstichting/dr. Ludgardine Bouwmanstichting

Intervention

Keyword: colon cancer, in vivo, sentinel node

Outcome measures

Primary outcome

Number of successful SN-procedures.

Secondary outcome

Number of problems encountered during the SN-procedure. Number of resected and examined lymph nodes in the SN-group and the standard group. Number of examined lymph nodes when the pathologist is handed a X-ray of the specimen.

Study description

Background summary

In the Netherlands colorectal cancer is a significant cause of morbidity and mortality. Lymph node involvement is the most important predictor of prognosis. The five-year survival rate for stage I and II is 70-90%, but only 45-50% in case of metastatic spread to lymph nodes (stage III). Adjuvant chemotherapy improves the five-year survival in this last group. Recurrence after resection occurs in 20-30%, possibly because of understaging in case of undetected occult metastases. The sentinel node can facilitate time consuming and expensive pathological examination by identifying single lymph nodes that harbor the greatest potential of metastasis and visualize aberrant lymphatic drainage. This may lead to an increased number of resected and analyzed lymph nodes, which itself, is a prognostic variable on outcome. The SN-procedure may lead to a better selection of high-risk patients who could benefit from additional adjuvant treatment.

Study objective

The primary objective is to determine the feasibility of the in vivo sentinel node procedure in patients with colon carcinoma, during open and minimal invasive surgery.

The secondary objective of the study is awareness and knowledge of (non)sentinel nodes in colon cancer. The third objective is whether or not a X-ray of the specimen will increase the lymph node yield after a dissection is performed.

Study design

The study is designed as a prospective, single centre pilot, consisting of 2 SN-groups of 10 patients that will undergo open or minimal invasive surgery. And a control group of 10 specimens of patients treated earlier this year. In the SN-groups 1 cc of patent blue will be injected in the wall of the bowel near the tumor, with identifying of the SN and resecting it separately. The SN will be tested not only with HE-staining but also IHC and RT-PCR and in some cases a X-ray of the specimen will be added.

Study burden and risks

The burden consists of about 30 minutes of providing information on the study and time to read and sign the informed consent. Benefits are more accurate staging of the disease enabling more adequate additional treatment. Risks are mild to severe allergic reactions to patent blue, which can be treated adequately with the usual therapeutics and the potential risk of extension of the duration of the surgery.

Contacts

Public
Academisch Medisch Centrum

meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Resectabel colon cancer treated with segmental colectomy, in an elective setting, open or minimal invasive.
>18 years
ASA I-III
no known allergy for patent blue

Exclusion criteria

rectal cancer
earlier colonic surgery
pregnancy
age <18 years
emergency surgery
earlier chemo- or radiotherapy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL29174.018.09