Detection of disseminated tumor cells in bone marrow in patients with colon cancer

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To determine the feasiblity of the detection of disseminated tumor cells in bone marrow with RT-qPCR

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

Summary

ID

NL-OMON30951

Source
ToetsingOnline

Brief title
disseminated tumor cells in bone marrow

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
colon cancer, coloncarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: commissie wetenschappelijk onderzoek jeroen bosch ziekenhuis

Intervention

Keyword: bone marrow, colon cancer, disseminated tumor cells

Outcome measures

Primary outcome

The presence of disseminated tumor cells in bone marrow, which means an

elevated signal of CK20 and CEA in the RT-qPCR.

Secondary outcome

none

Study description

Background summary

Colon cancer is one of the most common cancer in the Netherlands. The most important predictor of survival is the presence of lymph node or distant metastasis.
Still, in 30-45% of the patients with curatively resected colon cancer with no lymph node involvement, local regional recurrence or distant metastasis will occur.
A plausible explanation could be the dissemination of tumor cells via blood or lymphatic system.
A method for detection of disseminated tumor cells is RT-qPCR. With RT-qPCR it is possible to detect specific genetic markers on tumor cells. In colon carcinoma, the expression of the genetic markers CK-20 and CEA are often elevated.
Since metastasis occur mainly via blood stream and the lymphatic system, tumor cells can be found in blood and bone marrow.

Study objective

To determine the feasiblity of the detection of disseminated tumor cells in bone marrow with RT-qPCR

Study design

During surgery, two bone marrow needle aspiration are performed, when the patient is under full anesthesia. The puncture site is the spina illiaca

anetrior superior. The first punction will be performed during surgey, when the tumor has not yet been resected. The second puncture will be performed as soon as the specimen is out of the patient.
The aspirated bone marrow will be conserved in a special medium en be brought to the laboratory. Here, the RT-qPCR will be performed and the aspirated bone marrow will be analysed for the presence of tumor cells.

Study burden and risks

The bone marrow aspiration will be performed during surgery by the operating surgeon under a sterile environment. The actual surgery will not take extra time. Also, the risk of infection is minimalised by performing the procedure under sterile conditions.
After an needel aspiration, there's a risk of hemorrhage. This risk is no greater than after an arterial punction. After aspirating bone marrow, the aspiration site will be compressed and a pressure bandag will be applied.

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

proven colon carcinoma
no pre-operative suspicion of distant metastasis
older than 18 years
written informed consent given

Exclusion criteria

distant metastasis
irresectable tumors
hemophilia
disseminated intravascular coagulopathy
no informed consent given
younger than 18 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	10
Type:	Actual

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	NL18942.028.07