

Radiolabeled bevacizumab as a tracer of VEGF expression in patients with colorectal liver metastases

Published: 04-05-2006

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Evaluation of tumor localization of In-111 labeled bevacizumab and possible correlation with VEGF expression in patients with colorectal liver metastases.

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

Summary

ID

NL-OMON29757

Source

ToetsingOnline

Brief title

Avastin-scanning in patients with colorectal liver metastases

Condition

- Metastases

Synonym

colorectal liver metastases

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Avastin, bevacizumab, radioactive tracer, VEGF

Outcome measures

Primary outcome

Correlation of In-111 labeled bevacizumab and histological VEGF expression.

Secondary outcome

Not applicable.

Study description

Background summary

Variable response to angiogenesis inhibitors; the need of a non-invasive way of selecting patients for this treatment.

Study objective

Evaluation of tumor localization of In-111 labeled bevacizumab and possible correlation with VEGF expression in patients with colorectal liver metastases.

Study design

Administration of In-111 labeled bevacizumab, followed by 2 total body scans. After resection the tumor will be analyzed immunohistochemically.

Study burden and risks

Small risk of side effects of bevacizumab. Burden: 2 hospital visits of 3-4 hours each.

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 liver metastases, planned surgical resection within 6 weeks.

Exclusion criteria

Pregnancy, lactation, recent chemotherapy (within 3 months after last chemotherapy regimen).

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):	01-05-2006
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	In-111 labeled bevacizumab
Product type:	Medicine
Brand name:	Avastin
Generic name:	bevacizumab
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	04-05-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	11-05-2007
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2006-002044-29-NL
CCMO	NL12163.091.06