

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

Public

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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 |