# Laparoscopische Intra-operatieve fluorescente beeldvorming van oogmelanoom lever metastasen.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON22421

**Source**
NTR

**Brief title**
GREEN LIGHT

**Health condition**

Hepatic Uveal Melanoma Metastases

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center
**Source(s) of monetary or material Support:** Leiden University Medical Center

### Intervention

### Outcome measures

**Primary outcome**

Feasiility of Intra-operative identification of liver metastases.

**Secondary outcome**

Identification rate; defined as the number of tumours that were identified with the fluorescent signal of ICG during operation, compared with the number of microscopically Tumor to background ratio between different doses of ICG injected and different time intervals injected.

# Study description

### Background summary

One of the main challenges in liver surgery for uveal liver metastasis is intraoperative tumor detection. Especially intra-operative detection of small tumors has proven to be very difficult. Near-infrared fluorescent (NIRF) imaging is a recently developed method to visualize tumor tissue during surgery. Standard liver resection will be performed. The near-infrared dye ICG will be injected i.v. and liver tumors will be visualized using a laparoscopic NIRF imaging system.

### Study objective

Laparoscopic Fluorescent near-infrared imaging using ICG can accurately detect liver metastases from uveal melanoma intra operatively.

### Study design

The primary and secondary outcomes will be assessed during surgery and pathological assessment.

### Intervention

ICG will be administered 24hours before surgery. During laparoscopic surgery, liver metastases will be visualised using near-infrared fluorescence imaging and standard liver resection will be performed.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Patients diagnosed with uveal melanoma liver metastasis that are eligible for resection;

2. Age between 18 and 80 years old.

## Exclusion criteria

1. No history of allergy to iodine, shellfish, indocyanine green, human serum albumin and/or history of hyperthyroidism or severe renal impairment;

2. Patient pregnant or lactating.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-09-2012 |
| Enrollment: | 15 |
| Type: | Anticipated |

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 21-02-2013 |
| Application type: | First submission |

## 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 |
|---|---|
| NTR-new | NL3700 |
| NTR-old | NTR3869 |
| Other | METC LUMC : P10.001 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

## Study results

#### Summary results

N/A