# Study for Intra-operative Imaging of Cancer using a New Fluorescent Agent

No registrations found.

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

## Summary

### ID

NL-OMON20365

**Source**
NTR

**Brief title**
n/a

**Health condition**

Ovarian Cancer; Endometrial Cancer; Renal Cell Cancer
Ovarium carcinoom; Endometrium carcinoom; Niercel carcinoom

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center and Centre for Human Drug Research, Leiden, the Netherlands
**Source(s) of monetary or material Support:** On Target Laboratories, LLC

### Intervention

### Outcome measures

**Primary outcome**

Tolerability / safety endpoints

Treatment-emergent adverse events (TEAEs) using MedDRA from the time of administration

throughout the study period, and changes in serum biochemistry, hematology, vital signs, ECG, injection site status, and physical examination findings.

**Secondary outcome**

Efficacy endpoints

1. TBR, defined as fluorescent signal of tumor tissue compared to fluorescence signal of tissue surrounding the tumor, at different doses;

2. Concordance between the pathology results with respect to the presence of cancer and the imaging assessment;

3. Number and location of FR-a+, cancer+ tumor lesions and resection margins identified under usual visual/tactile conditions, under both usual visual/tactile conditions and fluorescent light, and under fluorescent light only

4. Surgeons' opinion regarding utility of IV OTL-038 injection and imaging system

Pharmacokinetic endpoints

Cmax, T½, AUC, Tmax, Clearance

# Study description

**Background summary**

It is important to improve visualization of tumors and metastases, such as in ovarian, renal cell and endometrial cancer, in real time during surgery to enable the surgeon to excise more of the tumor, and also to facilitate proper staging. Intra-operative identification of cancer tissue using new real-time imaging modalities that could provide clear tumor identification and demarcation would provide a very useful tool to reduce positive resection margins and increase full removal of the tumor hence reducing rates of re-interventions and therefore may reduce morbidity and improve patient outcome. Furthermore, if otherwise invisible tumor lesions and metastasis can be identified, tumor staging will be possibly improved which influences treatment choices. In the last few years, a novel optical imaging platform has emerged. The use of fluorescent probes that recognize cancer-specific antigens, in conjunction with a clinical imaging system, are under investigation. OTL38, a fluorescent probe that targets the folate receptor alpha (FRa), a receptor over-expressed in most ovarian, renal and serous and clear cell endometrial cancers, and that emits lights with wavelengths in the near-infrared (NIR) spectrum, along with an imaging system, can be used to visualize FRa positive cancer in patients during surgery. This could enable the surgeon to excise more

of the tumor tissue as compared to usual visual and tactile methods.

**Study objective**

1. To assess the safety and tolerability of different doses of a single IV injection of OTL-038

2. To assess the efficacy of ascending doses of a single IV injection of OTL-038 in detecting ovarian, renal cell or endometrial cancer during surgery by :

a. Tumor to background ratio (TBR)

b. Concordance between fluorescent signal and tumor status of resected tissue

c. Detection of more FR-a+, cancer+ tumor lesions or resection margins with fluorescent light compared to usual visual/tactile conditions

3. To assess the surgeons' opinion regarding the utility of OTL-038 IV injection and imaging system in debulking or staging of ovarian cancer or endometrial cancer or surgical removal of renal cell cancer

4. To assess the pharmacokinetics of ascending doses of a single IV injection of OTL-038

**Study design**

Visit 1 (Screening, up to Day -60)

Provide written informed consent; complete medical history and physical examination; vital signs and weight; ECG tracing; clinical hematology and chemistry laboratory assessments; blood pregnancy test for females of child-bearing potential; and collection of concomitant medication information

Visit 2 (Day of surgery)

A single dose of OTL-038 will be administered IV over 60 minutes to each subject two to three hours prior to surgery.
Blood samples for assessment of OTL-038 PK will be taken at time points specified in the schedule of assessments. Planned surgery will be performed during which real-time imaging of the lesions utilizing a fluorescent imaging system will be done.

Visit 2 (After surgery, admission day Day 2)

Routine-post surgical follow-up with dedicated assessment of any AEs up to 24 hours will

occur. Patients will be hospitalized post-operatively per routine standard of care and blood samples for routine analyses will be taken as part of standard of care. And at 24 hours post dosing a last PK sample will be obtained.

Visit 3 (Follow up)

Telephonic follow up with dedicated assessment of AEs and concomitant medication.

**Intervention**

Single IV injection of OTL38 at doses of 0.0125, 0.025, 0.05 and 0.1mg/kg bodyweight

# Contacts

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# Eligibility criteria

## Inclusion criteria

Inclusion criteria ovarian cancer:

1. Known or high clinical suspicion of primary ovarian cancer planned for either primary debulking surgery or interval debulking surgery by laparotomy (18 patients)

2. Clinical suspicion of primary epithelial ovarian cancer planned for either laparoscopic or open staging procedure or laparoscopic procedure to determine optimal primary treatment (debulking surgery procedure vs neo-adjuvant chemotherapy)

Inclusion criteria renal cell cancer:

1. Known or high clinical suspicion of primary renal cell carcinoma planned for either primary radical nephrectomy by laparotomy or laparoscopy or partial nephrectomy by laparoscopy

Inclusion criteria endometrial cancer:

1. Known or high clinical suspicion of primary serous or clear cell endometrial carcinoma planned for either staging or debulking surgery by laparotomy or laparoscopy

Inclusion criteria general:

1. 18 years of age and older

2. Normal or clinically acceptable medical history, physical examination (including vital signs), and laboratory tests at screening

3. Patients are clinically fit for surgery

## Exclusion criteria

1. Any condition that in the opinion of the investigators could potentially jeopardize the health status of the patient

2. History of anaphylactic reactions or severe allergies

3. History of allergy to any of the components of OTL38, including folic acid

4. Pregnancy, or positive pregnancy test

5. Clinically significant abnormalities in ECG and/or clinical laboratory test results

6. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

7. Impaired renal function defined as eGFR<50 ml/min/1.73m2

8. Impaired liver function defined as values greater than 3x the upper limit of normal (ULN) for ALT, AST, or total bilirubin.

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 22-09-2014 |
| Enrollment: | 0 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 15-01-2016 |
| 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 | NL5548 |
| NTR-old | NTR5669 |
| Other | NL49686.058.14 : P14.157 |

# Study results

**Summary results**
n/a