Real-time intraoperatieve detectie van ureters.

No registrations found.

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

Summary

ID

NL-OMON20719

Source
NTR

Brief title
GREEN LIGHT

Health condition

ureteral damage, Near infrared fluorescence imaging, Methylene blue

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Intra-operative identification rate, defined as the number of ureters that were identified with the fluorescent signal of methylene blue during operation.

Secondary outcome

1. Signal-to-background signal of the identified ureters;

2. Difference between dose groups.

Study description

Background summary

Iatrogenous ureteral injury is a rare, but serious complication of lower abdominal surgery. Ureteral damage is often missed and it can lead to severe morbidity such as genitourinary fistula formation or major renal complications. Near-infrared (NIR) fluorescence imaging is a promising technique that offers intraoperative, real-time, visual information during surgery. Methylene blue (MB) becomes a moderate-strength fluorophore emitting at ¡Ö 700 nm when diluted to levels that are almost undetectable to the human eye. Since MB is cleared renally, we hypothesized that low-dose MB can be used as a NIR fluorescent tracer for intraoperative identification of the ureters.

Study objective

Fluorescent near-infrared imaging can be used to identify the ureters using a low dose methylene blue.

Study design

The primary and secondary outcomes will be assessed during surgery.

Intervention

Patients will receive standard of care. During surgery, methylene blue will be injected intravenously to identify the ureters using NIR fluorenscence.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients planned to undergo surgery in the lower abdomen;

2. Minimum age of 18.

Exclusion criteria

1. Allergy for Methylene blue;

2. Patients using SSRIs, SNRIs of TCAs;

3. Pregnancy;

4. Severe renal impairment;

5. Patients with a G6PD deficiency.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	13-06-2012
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	NL3349
NTR-old	NTR3481
Other	METC LUMC : P10.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A