The use of Near-Infrared Fluorescence Imaging in parathyroid visualization during Thyroid Surgery: a pilot study

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The main goal of this pilot study is to investigate the feasibility of the identification of the parathyroid glands by means of the present commercially available near infrared fluorescence imaging system during thyroid surgery: is it possible to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON45992

Source
ToetsingOnline

Brief title
NIRF imaging of the parathyroid glands

Condition

- Thyroid gland disorders
- Endocrine gland therapeutic procedures

Synonym
thyroid disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Indocyanine Green (ICG), Near Infrared Fluorescence Imaging (NIRF), Parathyroid, Thyroid surgery

Outcome measures

Primary outcome

The main goal of this pilot study is to investigate the feasibility of

identification of the parathyroid glands with fluorescence imaging equipment

with per-operative ICG administration.

Secondary outcome

Angiography of the parathyroid glands after resection of thyroid.

Quantitative measurement of fluorescence signal using Target to Background

Ratio (TBR)

Calcium levels postoperatively day 1 and day 2 and after two weeks after total

thyroidectomy

PTH levels postoperatively after two weeks after total thyroidectomy

Histology: are parathyroid glands in the specimen?

Subjective opinion surgeon about the usefulness of the technique

Time measurement:

* Time until identification of first parathyroid gland

* Time until identification of all four parathyroid glands

* Total operation time (time from incision till closure)

Differences between the two used systems (Karl Storz and Quest Medical Imaging)

Intraoperative complications due to the use of the technique

Study description

Background summary

Surgical procedures involving the thyroid gland require identification of the parathyroid glands. However, these glands are small and can be difficult to distinguish from normal fat tissue and lymph nodes around the thyroid gland. Identification of the parathyroid glands therefore, takes considerable surgical time. Despite the efforts of endocrine surgeons to preserve the parathyroid glands, iatrogenic hypoparathyroidism is a common complication following thyroidectomy, occurring in up to 15% of patients. Hypoparathyroidism can result in hypocalcemia. Severe hypocalcemia can result in cardiac arrhythmias and tetany, increased morbidity, prolonged duration of hospitalization and death. Identification of the parathyroid glands during thyroid surgery may prevent their inadvertent surgical removal and thus provide a better postoperative outcome and quality of life. Recently, a case report and earlier a dog study is published which both show promising results in the use of NIRF for identification of the parathyroid glands.

Another desire is to not only recognize the parathyroid gland during surgery, but also knowing whether the function of the parathyroid gland is appropriate. The functioning of the preserved parathyroid glands seems to be dependent on the vascularization of the glands. ICG angiography is used already in anastomotic bowel surgery and to visualize the cystic artery. Fortunity et al investigated the applicability of NIRF with ICG in the assessment of the perfusion of the parathyroid gland. The results of this article are promising.

Our hypothesis is, that the use of ICG-based fluorescence imaging during thyroid surgery will provide a real-time intraoperative visualization of the parathyroid glands. This will improve patient safety by avoiding complications related to misidentification of the parathyroid glands, and might decrease surgical time. Furthermore, ICG based fluorescence angiography after thyroid removal can be a used as a reassurance whether the (vascularization of) the parathyroid is still intact.

Study objective

The main goal of this pilot study is to investigate the feasibility of the identification of the parathyroid glands by means of the present commercially available near infrared fluorescence imaging system during thyroid surgery: is it possible to obtain real-time clearer and earlier identification of the parathyroid glands in comparison to conventional surgery without the use of ICG?

A second objective is to investigate the use of fluorescence angiography of the parathyroid after thyroid removal: does it predict the postoperative outcome

concerning parathyroid hormone?

Study design

A prospective feasibility study
The study will be conducted in the Maastricht University Medical Center (MUMC)
The surgery will be performed by or under supervision of experienced endocrine-surgeons.
Video recordings will be made during the procedure after ICG injection:
1. During identification of the parathyroid glands
2. After resection of the thyroid to visualize the perfusion

After surgery the NIRF technique will be assessed using the intraoperative registration form (See attachment) and visual recordings will be analyzed. Additionally, on postoperative day 1 and 2 and after two weeks calcium levels will be determined, together with TSH level after two weeks in patients after total thyroidectomy as in standard care.

Intervention

The VITOM Fluorescence exoscope will be used during surgery. and in 30 patients simultaneously the Quest Spectrum Platform.
For this, a dose of 7.5 mg ICG will be administered intravenously at least two times at the following moments:
- during the resection of the thyroid for identification of the parathyroid glands
- after resection of the thyroid for assessment of the perfusion of the parathyroid glands.

As in standard care, postoperatively on day 1 and 2 and after two weeks blood levels of calcium are measured, together wit TSH after two weeks.

Study burden and risks

Compared with standard care, patients will undergo the following extra procedures:
- The VITOM exoscope will be used during surgery and in 30 patients simultaneously the Quest Spectrum Platform.
- At least two times as dose of 7.5mg will be administered intravenously

The outer outcomeparamters will be obtained from the patients medical dosier (pathology report concerning presence of parathyroidglands in resected thyroid (part) and postoperative calcium levels and TSH levels as determined in standard care).

It is known that injection of ICG preparations, in very rare cases, can cause nausea and anaphylactoid or anaphylactic reactions (<1:10,000). Patients with terminal renal insufficiency seem to be more prone for such an anaphylactic reaction.

The VITOM NIRF exoscope and Quest Spectrum Platform are both not related to additional risk for the patient.

Initially, patients participating in this study will not benefit from the application of NIRF during the surgical procedure.

We have a small sample size of 30 as it is expected that the outcome of this first feasibility study in this applicability of NIRF will be of great importance for the further application of this technique, and can therefore be the basis for future research qualifying the possible advantages of the technique.

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

• Male or female patients, aged 18 years and above
• Scheduled for elective total or hemi thyroidectomy
• Normal liver and renal function
• No known hypersensitivity for iodine, ICG, sulfa- or penicillin allergy
• Able to understand the nature of the study procedures
• Willing to participate and give written informed consent

Exclusion criteria

• Age < 18 years
• Liver or renal insufficiency
• Known iodide, ICG, sulfa- or penicillin hypersensitivity
• Pregnancy or breastfeeding
• Not able to understand the nature of the study procedure
• i.v. heparine injection in the last 24h (LMWH not contraindicated)
• Not willing to participate

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-03-2017
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	VITOM Fluorescence Imaging System en Quest Spectrum Platform
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-10-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-10-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL57409.068.16