The use of an iodine 125 marker for perioperative localization in primary hyperparathyroidism, a pilot study.

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To facilitate the localization of a parathyroid adenome during surgery (MIP) with a radioactive iodine 125 (I-125) marker. This marker is placed preoperatively ultrasound guided in the affected parathyroid gland, and can be detected with a gamma...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Parathyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON36945

Source
ToetsingOnline

Brief title
I-125 marker localization in primary hyperparathyroidism.

Condition

- Parathyroid gland disorders

Synonym
parathyroid tumor, primary hyperparathyroidism

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Ziekenhuis wetenschapsfonds

Intervention

Keyword: I-125 marker, localization, primary hyperparathyoidism, surgery

Outcome measures

Primary outcome

All data are recorded prospectively. Patient characteristics, indication for surgery (MIP), placement of the I-125 marker (complications, time, difficulty, displacement of the marker), intraoperative data (time to find the marker, blood loss, operative time, use of NIM, occurring of migration, distance to parathyroid / thyroid) and the results of the final pathologic study (diagnosis, radical, effect on parathyroid / thyroid) will be recorded.

All data will be analyzed and processed in SPSS. It is a prospective study to describe the feasability of I-125 markers in parathryoid surgery.

Secondary outcome

not applicable

Study description

Background summary

The parathyroid glands provide the calcium metabolism in the human body through the regulation of parathormone. Most people have four parathyroid glands, two cranial and two caudal to the thyroid. However, 4-22% of those people have more than four parathyroid glands. Primary hyperparathyroidism (PHPT) occurs if too much parathyroid hormone is produced resulting in an increased calcium. The diagnosis is made on biochemical abnormalities with an elevated serum calcium and increased PTH. Causes of PHPT are mostly a solitary adenoma (~ 80-90%), sometimes multiple adenomas (~ 5%), multiple hyperplasia (~ 5 - 10%), rarely thyroid carcinoma (1%) and familiar in the context of a MEN 1 or MEN 2A syndrome (~ 4.5%). Preoperative diagnostic tools are ultrasound and

thyroidscintigraphy. However, a CT scan or an MRI are also possible. The treatment options for primary hyperparathyroidism are mainly surgical. If there is a preoperative suspicion of a solitary adenoma in one of the parathyroid glands, it is preferred to perform a minimally invasive parathyroidectomy (MIP). With a MIP the surgeon makes a small incision in the neck above the preoperatively localized parathyroid to find the adenoma and resects it. This is in contrast with the conventional neck exploration in which the entire neck is explored to search for one or more affected parathyroid glands. Parathyroid glands can be localized on their entire embryological route in the neck and mediastinum, so it can be difficult to localize parathyroid glands during surgery. It is therefore important to perform a pre-operative localization before a parathyroidectomy. Especially in a patient who has been operated in the neck, localizing the affected parathyroid can cause problems with an increased risk of damage to surrounding structures such as the recurrent laryngeal nerve. There are several methods described to localize to the parathyroid glands. A common method is preoperative marking using ultrasound pre- or intraoperatively. This is a cheap, non-invasive and highly sensitive technique in experienced hands. A different localization method has been the use of 99m Tc-sestamibiscan. This technique requires a gamma probe intraoperatively and logistic adjustment, because the injection of 99mTc has to be performed on the same day as the operation should take place. There is also an increased exposure to radioactive material. Taking into account the logistical problems, this is in our view, certainly of importance in the treatment of the patient. The most common method, the ultrasound marker, is placed briefly prior to the surgery and is performed by the radiologist. This requires proper planning in according to localization and surgery. In our hospital localization is often not done for a minimally invasive procedure, in cases where the preoperative diagnostics are good and clear. This comes together with a potential risk of reoperation or even a conventional neck exploration is required, with more risks and an increased morbidity.

Study objective

To facilitate the localization of a parathyroid adenome during surgery (MIP) with a radioactive iodine 125 (I-125) marker. This marker is placed preoperatively ultrasound guided in the affected parathyroid gland, and can be detected with a gamma probe. It is a cylindrical seed with a length of 4 mm and a diameter of 0.8 mm, consisting of a titanium capsule containing material with radioactive iodine-125. There are no studies or centers known which uses this technique for preoperative localization of parathyroid.

The question we want to answer in this pilot study is twofold:
1. Is it possible to (safely) place iodine markers in the affected parathyroid gland(s)? Without the migration of the iodine marker?
2. Is it possible to locate the iodine marker during a parathyroidectomy procedure and perform a resection of the affected parathyroid gland? Does it facilitate a minimally invasive parathyroidectomy, with a high success rate (>

95%) and with a low(er) risk of collateral damage?

Study design

Patients in whom primary hyperparathyroidism was diagnozed due to an adenoma / hyperplasia / carcinoma, where a parathyroidectomy is indicated (symptomatic or progressive asymptomatic), are eligible for localization with I-125. Because we want to carry out a pilot study, a randomization between conventional ultrasound-guided marking and an I-125 marker has not been performed. If this study shows a safe use of an I-125 marker (ie, a similar risk of bleeding and surgical yield as ultrasound-guided marking), the following study will consist of a randomized study. The use of an I-125 marker will be compared with the standard procedure (ultrasound-guided marking).

The indication for a MIP (with I-125 marking) is set by endocrinologists, head and neck surgeons, radiologists and nuclear medicine physicians after a multidisciplinary meeting that takes place once in every two weeks. If a patient is eligible for a MIP with I-125 marker, this will be first discussed by the endocrinologist and then by the head-neck surgeon with the patient. Then the patient receives an information leaflet with an informed consent form. Afterwards a conversation with one of the researchers is offered to the patient. If the patient agrees, he will be included and a day will be scheduled when both the I-125 marking and the surgery (MIP) will take place. At any time the patient has all the rights to withdraw from the study. In that case, the standard procedure is performed (ultrasound-guided marking and MIP). Enrolled patients are insured by Medirisk. We choose in this study not to deviate from the logistical situation as it exists in our hospital. This means that the I-125 marker and the operation will take place on the same day. It is possible that this may change in the future.

The placement of the I-125 marker is done by the radiologist and the endocrinologist under ultrasound-guidens, preferably if possible in beachchair position. If problems arise during the placement of the I-125 marker, depending on the symptoms (direct) treatment is performed. The most common complication is bleeding, however, asymptomatic and therefore require mostly no (direct) treatment.

During the MIP procedure we will use a gamma probe (PI Medical Diagnostic Equipment BV), to detect the I-125 marker. If the marker is localized (and thus also the parathyroid gland) a resection will be performed. Then, a specimen X-ray of the removed parathyroid tissue is made. This to capture and verify the I-125 marker was actually removed from the patient. In addition, with the gamma probe will be checked whether there is still radioactivity present in the patient.The removed piece of parathyroid tissue is isolated and brought to the anatomic pathology laboratory. They will safely remove the I-125 marker and store it like described in the specific protocols.

After surgery, the patient received standard of care after parathyroid surgery in the surgical ward. The postoperative treatment is determined by the endocrinologist and head-neck surgeon. The final results of the pathology will be discussed with the patient by the head-neck surgeon.

The use of these radioactive I-125 markers, is because of its activity (about 10 MBq), placed under the Nuclear Energy Authorization from the Amphia Hospital. One of its requirements is that there is a good accounting of these I-125 markers. The loss of an I-125 marker can lead to several problems. The radiation protection / logistical support and management of the I-125 markers is managed under the supervisory radiation specialist of Nuclear Medicine. Since 2009 we are using the I-125 marker in breast surgery and since 2011 in lung surgery. The placement of iodine markers has therefore been everyday practice for the radiologists. In the operating room, the use of the gamma probe and the removal of tissue (with an iodine marker) from the operating room to the pathology laboratory is a well known practice nowadays.

Intervention

The placement of an I-125 marker for the localization of a parathyroid gland ultrasound guided.

Study burden and risks

Burden for the patient: additional information regarding explaintion of the study

Risks of I-125 marker placement: possible minor bleeding, which is usually asymptomatic and usually does not need (direct) treatment. The risk of remaining the iodine marker is minimal, due to direct intraoperative control of the specimen by means of X-rays. If the marker is not present in the specimen, the surgeon immediately continues to search for the marker in the patient.

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL
Scientific
Amphia Ziekenhuis

Molengracht 21
Breda 4818CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

primary hyperparathyroidism, age >18 year, and a parathyroid adenoma that can be localised by ultrasound in the neck

Exclusion criteria

age <18 year, secundairy and tertiary hyperparathyroidy and a non visible parathyroid adenoma by ultrasound.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL42021.015.12

Study results

Date completed:	15-03-2015
Actual enrolment:	10