Comparison of two methods to improve the outcome of a ultrasound assisted fine needle aspiration biopsy (FNAB) of the thyroid gland.

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Primary objective: - obtain an comparison in diagnostic results of two methods of ultrasound assisted fine needle aspiration biopsies (FNAB) of the thyroidal gland in the Jeroen Bosch hospital (JBZ).Secondary objective:- can the cytological thyroid...

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

Summary

ID

NL-OMON50480

Source
ToetsingOnline

Brief title
Thyrocore

Condition

- Thyroid gland disorders

Synonym
thyroid lumb, thyroid nodule

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: importeur (RMS medical devices) stelt aantal apparaten gratis ter beschikking

Intervention

Keyword: Cytocore, Cytology, Diagnostic, Thyroid

Outcome measures

Primary outcome

There will be 140 FNAB*s with both methods (A and B). The methods are compared

with each other on the basis of the diagnostic yield.

Secondary outcome

After 20 biopsies, the material is assessed again by the laboratory according

to the Bethesda criteria and additional 'evaluability/quality' criteria. The

laboratory will be *blind* to the method which is used to obtain de cytological

material. The quality of the cytological material is a secondary endpoint.

Study description

Background summary

To cytopathologically diagnose a thyroidal gland nodule the golden standard is to perform a (ultrasound guided) fine needle aspiration biopsy (FNAB) [4] [5]. At the laboratory the cytological material will be interpreted and classified according to the Bethesda system [3] [4]. Within this classification there are six categories (figure 1).

This research mainly concerns the category Bethesda 1, *non diagnostic*. As can be seen in figure 1, the risk of malignancy in this group is small, but it is recommended to repeat the ultrasound examination and perform a new FNAB [4] [6]. This leads to having to repeat an unpleasant examination for the patient, extra procedure-related risks, uncertainty about the results and possible consequences, not to forget also new appointments in the hospital (internist and radiology) are made. In addition to the adverse consequences for the patient, there are also additional costs, such as costs for the ultrasound

guided thyroid FNAB, pathological examination and an appointment with referring specialist(s). If the 'non-diagnostic' percentage could be reduced, this is not only a huge benefit for the patient, but also in favour of healthcare costs.
In 2012, an inventory was made among healthcare professionals regarding the thyroid carcinoma guideline in the Netherlands. In this inventory 53 out of 116 respondents indicated that they experienced the ultrasound with FNAB as a bottleneck. Of these 53 respondents, 18 considered this the most important hindrance [7]. Indirectly you can say that cytology is part of this hindrance.

According to literature, you can assume a variation in 'non-diagnostic yield' of approximately 5-25% for a FNAB of the thyroid gland [6] [8] [9] [10] [11] [12] [13] [14] [15]. In the Jeroen Bosch hospital approximately 50% of thyroid biopsies are performed by a PA radiology with a non-diagnostic yield of approximately 13-18% over n=700 patients. This corresponds to literature.

In the Jeroen Bosch hospital, an agreement has been made between radiologists, internists and pathologists to perform a fine needle aspiration biopsy of every thyroid nodule twice in order to minimize the chance of a non-diagnostic result. A thyroid FNAB is done under ultrasound guidance on the radiology department. During the biopsy, the nodule is punctured twice with a 25 Gauge needle. When the needle is in position in the thyroid, the present laboratory technician applies vacuum to the needle and at the same time the doctor/PA moves the needle gently up and down in the thyroid nodule with a rotating movement.

A device has been developed in America, the Cytocore, which provides vacuum to the needle and needle rotation in one act. The preliminary results show a clear improvement in the diagnostic yield of the biopsy (appendix 1). The cytological material contains more assessable cells and does not create any additional risk.

There is currently no literature available on the possible gain in yield for cytological biopsies of the thyroid gland by using the CytoCore. There is however a 'CytoCore white paper' on cytological biopsy of a pig liver, in which the use of the CytoCore caused less blood loss and increased cellularity of the cytological material (appendix 1). In addition, manufacturer Praxis, mentions that clinical feedback shows that 100% of the material was adequate for diagnosis (appendix 1). This sounds to good to be through and therefore before to introduce this promising device in clinical practice we would like to investigate its technical and diagnostic efficacy.

Study objective

Primary objective:
- obtain an comparison in diagnostic results of two methods of ultrasound assisted fine needle aspiration biopsies (FNAB) of the thyroidal gland in the Jeroen Bosch hospital (JBZ).
Secondary objective:

- can the cytological thyroid material obtained with the CytoCore (method B) be better assessed under the microscope in comparison with the material obtained manually (method A)?

Study design

This is a randomized prospective cohort study. With an ultrasound guided thyroid FNAB, the thyroid nodule is standard biopsied twice with a 25 Gauge needle. The intervention consists of replacing 1 standard biopsy (method A) by a biopsy with the CytoCore (method B). In both cases the same standard 25 Gauge needle is used. Randomization determines with which method the first and second biopsy is performed, this creates 2 possibilities. The first possibility is a standard biopsy (method A) at first followed by a CytoCore biopsy (method B). The second possibility is at first a biopsy with CytoCore (method B) followed by a standard biopsy (method A). Randomization is performed for the 140 participants via http://www.randomization.com (appendix 2). The randomization is divided into 7 blocks of 20 participants so that after the first 20 participants method A and B are equally distributed for an additional assessment. If the randomization table shows an 'A' the first biopsy is done in the standard way (method A), if the table shows a 'B' the first biopsy is done with the CytoCore (method B). All cytological material is assessed according to the Bethesda criteria [3].

Intervention

The intervention consists of replacing one out of two standard thyroid FNAB*s (method A) with a thyroid FNAB using the CytoCore (method B).

Study burden and risks

No additional measures have been taken for the use of the CytoCore. The product meets the requirements set by the JBZ. A prospective risk assessment for medical devices (PRS) has been performed, which indicated that no further risk analysis is required.
The standard 25 Gauge needle is used during the biopsy and there is no reason to believe that using the CytoCore would increase the risk of patients. The same kind of technique (rotating needle and negative pressure) is now also used. The CytoCore is used as intended and European approved.

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

18 years of older
Patient qualifies for thyroid FNAC

Exclusion criteria

17 years or younger
Patient does not qualifies for thyroid FNAC

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-05-2022
Enrollment:	140
Type:	Actual

Medical products/devices used

Generic name:	CytoCore
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-03-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-05-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL78909.028.21