Comparison of outcome with three different needles in ultrasound assisted fine needle aspiration cytology (FNAC) of the thyroidal gland.

Published: 19-12-2012
Last updated: 26-04-2024

Primary objective: to obtain an comparison of the diagnostic result after an ultrasound assisted fine needle aspiration cytology (FNAC) of the thyroidal gland by use of a smaller diameter (25G) and / or a special coating.

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

Summary

ID

NL-OMON37029

Source
ToetsingOnline

Brief title
FAMA

Condition

- Thyroid gland disorders
- Miscellaneous and site unspecified neoplasms benign

Synonym
benigne and maligne nodules of the thyroid gland

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: ziekenhuis

Intervention

Keyword: cytology, FNAC, thyroid, ultrasound

Outcome measures

Primary outcome

The main study parameter is to achieve a higher percentage of diagnostical-results. This goal will be achieved when the percentage diagnostical-result will increase. Because of the low current percentage diagnostical-result comparing to the national percentage mentioned in literature, the investigators wish to achieve an increased percentage of 5%. In this case the new percentage diagnostical-results will be 81%, and the investigators will speak of clinical relevance. Off course the higher the outcome, the better it will be for the patients. During the ultrasound assisted FNAC of the thyroidal gland, one of the three research needles will be used on the patient. When 112 patients per needle are included,336 in total, the endpoint of the study is reached. The question this study addresses is: can the diagnostic-result for a FNAC of the thyroidal gland be improved using a needle with a smaller diameter and/or a special coating?

For statistical analyses the number of *not-diagnostical* and *diagnostical* results will be reported. In this study two proportions are compared, based on the normal approximation to the binomial distribution. The equation used for

the sample size is:

N = 2 . [Zcrit *(2 pmean(1- pmean)) + Zpwr *(p1(1- p1) + p2 (1- p2))]2 / D2

Is this equation the following values were used:

p1 = 0.76

p2 = 0.90

pmean = 0.83

D = 0.14

Zcrit = 1.960 (significance criterion = 0.05)

Zpwr = 0.842 (power = 0.80)

The values p1 and p2 are the pre-study estimates based on the current diagnostical results by F. Pessers. His diagnostical percentage on the current needle is 76% and he tested one of the new needles with an outcome of 90%. In the study by F. Pessers (2012, January) the overall not-diagnostical percentage was 35,7%. The Zcrit and Zpwr are taken from table 1 and 2 in an article by Eng1.

The outcome of this equation: N = 112 per needle. The two groups comprising N are equal in number, and two-tailed statistical analysis will be used.

Two-tailed statistical analysis will be used because it is unknown whether or not the new needles will have a better diagnostical outcome in comparison to the currently used needle. The whole study population will be: 3x112=336.

Secondary outcome

n.v.t.

Study description

Background summary

To diagnose a thyroidal gland abnormality, at the Jeroen Bosch Hospital, an ultrasound assisted fine needle aspiration cytology (FNAC) takes place. A recent study by F. Pessers shows that the results of the fine needle aspiration cytology in this hospital are lower in comparison to the literature. In general, 8-20% of FNACs result in a *not-diagnostic* outcome. In this case the Radiologist did not retrieve enough thyroidal cells for the laboratory to diagnose the type of cells. The Jeroen Bosch Hospital has an outcome of 35,7% non-diagnostic material. The study by F. Pessers showed that use of different needles by different Radiologists result in a wide variety of non-diagnostic results. The lowest score was a 100% not-diagnostic rate, the highest score was a 0% not-diagnostic rate. Not every Radiologist performed the same amount of FNACs (this varies between 1 and 30). The higher the number of biopsies, the better the outcome.

The used needle diameters at the Jeroen Bosch Hospital varies between 18G (Gauge) and 27G (Gauge). The investigator thinks the percentage of diagnostic material can be improved by using a needle with a 25G diameter and/or by using a needle with a special coating that improves the capillary action.
This study will compare two needles with a smaller diameter and/or special coating to the currently used needle.
The power of the study should be at least 80% to get a statistic reliable research, therefore at least 336 patients will be included. Statistical significance will be assumed when the P value is < 0.05. Ninety-five percent confidence intervals will be calculated for proportions based on exact binomial tables. Statistical analysis will be performed with SPSS version 20.0 software (SPSS, Chicago, IL, USA).

The patient population will be divided into three equal groups randomly.
- 1. Currently used needle A: BD Microlance 3, 22Gx50 mm
- 2. New needle B: Inrad 25Gx40 mm, anticoagulantia coating Procytin*
- 3. New needle C: B.Braun sterican 25Gx40 mm.

Study objective

Primary objective: to obtain an comparison of the diagnostic result after an ultrasound assisted fine needle aspiration cytology (FNAC) of the thyroidal

gland by use of a smaller diameter (25G) and / or a special coating.

Study design

A interventional study design will be used for a comparison between three needles used in FNAC of the thyroidal gland. 336 patients with thyroid nodi and cysts will be included in the study. All patients who are redirected by the specialist or general practitioner with abnormalities in the thyroidal gland will be included in this study. Except patients who refuse to participate in the study and patients who are younger than 18 years. These patients will be informed about this study through a letter explaining the content of the study. After giving their written informed consent, the patients described above, are included in the study. The patients will undergo the FNAC of the thyroidal gland the same way as patients who will not be a part of the study. The only difference for the patient is the ad random selection of de needle which will be used during the fine needle aspiration cytology. The need for a FNAC of the thyroidal gland is decided by the treating doctor. However, if there are no abnormalities seen during the ultrasound the Physician Assistant will not perform a FNAC.

During the study the fine needle aspiration cytology of the thyroidal gland will be executed by only the Physician Assistant. In case F. Pessers (PA) is unable to execute the FNAC, an AIOS of the department of Radiology will execute the FNAC. F. Pessers is allowed to perform FNAC of the thyroidal gland within the Jeroen Bosch Ziekenhuis. This is not registered in the BIG-registration, but F. Pessers has a GAIA accreditation. There is also a competence declaration signed by a Radiologist which declares F. Pessers is allowed to perform FNAC of the thyroidal gland within the Jeroen Bosch Ziekenhuis).

The three needles used in this study are the:
1. Currently used needle A: BD Microlance3, 22Gx50mm
2. New needle B: Inrad 25Gx40mm, anticoagulantia coating Procytin*
3. New needle C: B.Braun sterican 25Gx40 mm

The obtained material will be sent to the pathological anatomical laboratory where it will be fixated and examined. If the results are *non-diagnostical*, the examination has to be repeated. Non-diagnostical material in this study means that the cytological material is insufficient either inadequate. Because of this, the pathologist is not able to interpret this material. When there are less than 6 groups of 10 cells each present, the cytological material is considered to be insufficient. In this case, there are not enough cells available for the pathologist to interpret. If the presence of one atypical cell is determined, the cytological material is considered to be diagnostic. One speaks of inadequate material when there are colloid cells present as well as follicular cells and in case blood is dominantly present in the cytological material. These are international guidelines, also know as the *Bethesda criteria*.

There are currently 5 pathologists active at the Jeroen Bosch Hospital who interpret the cytological material obtained by FNAC of the thyroid. They use the same guidelines and review the material they receive the same way. At this moment, there is no significant difference between the reviews of the 5 pathologists. The pathologists are not informed about the needle that is used on each patient. So their review will not be influenced. Rotation of the proceedings of each pathologist takes place. This way the average reviews of each pathologist is considered to be equal. After examining 150 patients (about 30 patients (± 5 patients) per pathologist) an evaluation will take place if the above is correct. If not, the laboratory will be informed and they will try to adjust their rotation schedule for an equal amount of reviews. The final result of the cytological outcome will be scored by the pathologist and introduced into our hospitals lab-results-system called Mirador.

Intervention

Patients will undergo a FNAC of the thyroidal gland the same way as other patients who will not participate in this study. The only difference is that there is a possibility another needle will be used. This will be determined by faith.

Study burden and risks

There are no risks involved. The examination will take about 30 minutes. Compared to the current exam, the burden for the patient will be the same. In case the first FNAC has a diagnostic outcome (vs. a non-diagnostic outcome), the burden for the patient will decrease.

Contacts

Public
Jeroen Bosch Ziekenhuis

Henri Dunantstaat 1
's-Hertogenbosch 5223 GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

Henri Dunantstaat 1
's-Hertogenbosch 5223 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with a thyroid nodule on ultrasound
Age greater than 18
Ability to give written informed consent

Exclusion criteria

Patient refusal

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2013
Enrollment:	336
Type:	Actual

Ethics review

Approved WMO Date:	19-12-2012
Application type:	First submission
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	NL41615.028.12