Clinical Management of patients with Afirma® Gene Expression Classifier for Thyroid Nodules with Indeterminate FNA Cytopathology

Published: 19-02-2016
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Objective: The purpose of this study is to compare the diagnostic surgical rate of a matched control group, derived from a retrospective review of patients without GEC testing, with a prospective GEC tested group.

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

Summary

ID

NL-OMON42612

Source
ToetsingOnline

Brief title
Gene Expression Classifier for Thyroid Nodules

Condition

- Thyroid gland disorders

Synonym
thyroid nodules

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Het is een investigator initiated study;op initiatief van de drie betreffende centra. Een belangrijk deel van het onderzoek zal daardoor worden uitgevoerd door mensen die reeds in dienst zijn van de betreffende academische ziekenhuizen. De firma Veracyte stelt de gen expressie test beschikbaar;en geeft daarnaast een tegemoetkoming in de kosten.,veracyte stelt de gen analyse gratis beschikbaar, en geeft daarnaast een tegemoetkoming in de ksoten van het onderzoek

Intervention

Keyword: FNA, gene analysis, thyroid

Outcome measures

Primary outcome

Main study parameters/endpoints: The primary study endpoint is the comparison

of diagnostic surgical rates between the historical control group (the

retrospective review of patients without GEC testing) and a prospective group

in which the GEC test is added to the regular clinical management of patients

with cytologically indeterminate nodules enrolled in this study.

Secondary outcome

Clinical data will be collected.

Study description

Background summary

Rationale: Approximately 15 to 30% of thyroid nodules evaluated by means of fine-needle aspirate biopsy (FNAB) are not clearly benign or malignant. Patients with cytological indeterminate nodules (Bethesda III/IV) are often referred for diagnostic surgery, though most of these nodules prove to be benign. A novel diagnostic test that measures the expression of 167 genes (the Afirma gene expression classifier (GEC)) has shown to identify many benign thyroid nodules accurately when FNA results were cytological indeterminate.

Study objective

Objective: The purpose of this study is to compare the diagnostic surgical rate

of a matched control group, derived from a retrospective review of patients without GEC testing, with a prospective GEC tested group.

Study design

Study design: We will perform a retrospective study to describe the clinical management of patients undergoing thyroid fine needle aspirate biopsy resulting in an indeterminate cytopathology diagnoses (Bethesda III/IV) in the absence of molecular diagnostic testing. The operative rate within the first year after FNAB will be calculated for this retrospective cohort. Next, prospectively, patients with indeterminate cytopathology will be offered GEC testing in the absence of other reasons to operate. Clinician(s) will receive the test result to incorporate into clinical decision making, and patients will then receive care as decided locally. Primary outcome is the percentage of patients who underwent diagnostic surgery. Prospective cases will be matched against historical controls. Matching will be performed blinded to the management outcome after FNA. The subjects will be matched according to the following characteristics: Age, gender, FNA result and hospital. Factors influencing the decision regarding surgery such as ultrasound characteristics, cytopathology and clinical findings, will be evaluated.

Study burden and risks

There are no extra risks associated with the GEC test other than the risks of FNA. Considering the major impact of surgery on quality of life, a significant reduction in the number of diagnostic surgeries will benefit a lot of patients. It will also prevent life-long replacement with levothyroxine which is often required after diagnostic surgery. The GEC test result is added to the regular clinical management as one of several factors for clinical decision making. A benign GEC result reduces the risk of malignancy to less than 6% justifying a wait and see policy in the majority of patients. This is currently the standard of care for patients with a Bethesda II FNA result, with have the same malignancy risk. All patients with a GEC benign result will be closely monitored with repeat ultrasound after 6 months and then annually for at least 5 years.

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

Patients will be eligible for inclusion in the study if the following criteria are met:
1. Patient with FNAB of a thyroid nodule with a Bethesda III or IV cytopathology diagnosis
2. Patient age at the time of FNAB was 18 or older
3. No adjunctive molecular testing has been performed on the thyroid nodule
4. There are no other reasons for which surgery is planned regardless of the cytopathologial results.

Exclusion criteria

1. Patient has other nodule(s) in thyroid known to have diagnosis of Bethesda V or VI cytopathology, or pathological lymphnodes indicative of thyroid malignancy.
2. Surgery is already likely or planned regardless of the FNAB result due to cosmesis, rapid nodule growth, symptoms, patient request or physician recommendation
3. There are reasons for which surgery not applicable regardless of the cytopathologial results.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2016
Enrollment:	69
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	04-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27479
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL54010.078.15
OMON	NL-OMON27479