The effect of aspiration during FNAC of the thyroid on adequacy of cytologic material

Published: 30-06-2010
Last updated: 02-05-2024

Our goal is to evaluate if this onsite assessment and aspiration during punction reduces inadequacy of specimens and see if onsite assessment by the aspirator is performed accurately after a brief instruction by a cytopathologist. Primary Objective...

Ethical review	Not approved
Status	Will not start
Health condition type	Thyroid gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34888

Source
ToetsingOnline

Brief title
Protact trial

Condition

- Thyroid gland disorders

Synonym
nodules/tumors of the thyroid, thyroid nodules

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,subsidie aanvraag Jan Dekkerstichting en dr. Ludgardine Bouwmanstichting

Intervention

Keyword: adequacy, aspiration, fine needle aspiration (FNA), thyroid

Outcome measures

Primary outcome

adequacy of cytologic material

Secondary outcome

accuracy of the primary assesment of cytologic material by the aspirator

other factors influencing adequacy rate

Study description

Background summary

Fine needle aspiration cytology (FNAC) is the current investigation of choice for nodules of the thyroid. It differentiates benign from malignant nodules and thereby selecting nodules for surgery. Major disadvantage of the procedure is the rate of inadequate or non-diagnostic specimen, resulting in diagnostic delay and discomfort for patients and increases costs for the institution. Ultrasound-guided FNAC is frequently advised as the procedure of choice in international literature. It is also advised in literature to frequently perform quality control in ones own institution.
Recent quality research in the UMC Utrecht, (manuscript submitted to American Journal of Clinical Pathology) showed a high percentage of inadequate ultrasound-guided FNAC specimen. Our investigation showed better results when radiologist performed aspiration during the procedure. It is still controversial in literature which method, aspiration versus non-aspirations yields the best results. Only two studies (Romitelli and Degirmenci) showed a better result of the non-aspirating capillary technique. (1;2)
In order to minimize costs and provide better health care, we would like to optimize the FNAC procedure, resulting in less inadequate specimens. In order to do so, we would like to identify which factors influence the adequacy rate. As advised by multiple studies we would like to, train puncturing specialist in identifying thyroid cells microscopically, so that onsite adequacy assessment can be performed.
Our hypothesis is: Aspiration during FNC and onsite cytologic assessment by the aspirator (=puncturing specialist) can be performed successfully and reduces

the rate of inadequate (or non-diagnostic) specimen drastically.

Study objective

Our goal is to evaluate if this onsite assessment and aspiration during punction reduces inadequacy of specimens and see if onsite assessment by the aspirator is performed accurately after a brief instruction by a cytopathologist.

Primary Objective:
Evaluation of the effect of aspiration on cytologic adequacy of fine needle aspiration of thyroid tissue.

Secondary Objective(s):
Identifying factors associated with cytologic adequacy of FNAC specimens
The effect of onsite interpretation on adequacy rate
To see if onsite interpretation of FNAC specimens of the thyroid can be performed accurately by the specialist also performing the punction (in this case: radiologist and residents).

Study design

The study design is that of a prospective cohort study. The study will be performed at the outpatient clinic where patients with thyroid nodules will be clustered on a specific day.

Every adult patient eligible for FNAC punction is also eligible for inclusion. Informed consent can be obtained after careful instructions and documented information after 2 weeks after the first policlinic visit.

After inclusion every patient will be randomized for a procedure. Smears will be carefully examined by the aspirator for material adequacy. Repeat punctions will be performed until the aspirator judges the material to be sufficient for definitive pathological analysis. All smears are send to the pathology department were they will be judged again on cytologic adequacy.

When material, after definitive cytopathologic examination is being judged as adequate, no further punctions will be performed unless regular follow-up with FNAC is required/advised.
When the material is judged inadequate after cytopathologic examination, the patient will have to undergo a repeat punction and will be again randomized for one of the two methods.

Data concerning patient, nodule, results of ultrasound, puncturing specialist, results of FNAC, results of onsite assessment and cytopathological analysis and final histology or follow-up will be obtained.

Cytopathologist will be blinded for the aspiration and non-aspiration smear. The aspirator will have to follow a short course provided by the pathology department to learn to identify thyreocytes microscopically.

Possible questionnaires will be distributed during hospital visit. There is no need for the patients to attend the hospital outside regular controls.

For now, the study period will be 2 years, with analysis of preliminary data after a year. In this period we expect to include more than enough patients for statistical significant outcomes.

Study burden and risks

When the best practise concerning FNAC is established, patients will have to undergo less punctions. Data from 1998 to 2008 showed a rate of inadequate FNAC specimen in the University Medical Center Utrecht of 46.2%. Repeated FNAC to reach an adequate specimen can be prevented. Thereby factors like patient discomfort, diagnostic delay, doctor*s frustration and costs for the institution can be reduced. Because of randomisation and inclusion of all patients eligible for thyroid FNAC results of this study can be generalised for a broader population.
There is no additional risk for the patient participating in this study, and no additional visits to the hospital have to be made.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3508 GA Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3508 GA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adult patients with nodules/tumors of the thyroid needing fine needle aspiration diagnostics

Exclusion criteria

Incapacitated patients

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	30-06-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL31562.041.10