The clinical benefit of thin layer preparations with endoscopic ultrasound-guided fine-needle aspiration of masses: a prospective cohort study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29425

Source
NTR

Brief title
The Cytolyt study

Health condition

EUS-FNA of a mass

endo-echografie van een massa

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

Diagnostic accuracy of EUS-FNA of masses with and without the thin layer preparation taken into account

Secondary outcome

Diagnostic adequacy

Cost-effectivity of thin layer preparation

Type of benefit from thin layer preparation

Study description

Background summary

In endoscopic ultrasound-with fine-needle aspiration (EUS-FNA) of masses, inserting part of the aspirate (or a separate aspirate) into CytoLyt is standard practice in our hospital, in addition to cytology slides. A thin layer preparation of this sample is then done in the pathology laboratory. It is not clear what the added value of such thin-layer preparation with CytoLyt is. Is This study is designed to examine the added value. In a 100 patients who undergo EUS-FNA of a mass, informed consent is asked. After the procedure, material is reviewed at a later time by two dedicated pathologists; first, only the cytology slides of a patient are reviewed, and a diagnosis is made if possible. Thus, a situation is simulated in which no thin-layer preparation is available. After this, the thin-layer preparation is given to the pathologists and all the material is again reviewed and a diagnosis is made if possible. samples are compared to the golden standard; surgical resection, histology or six months clinical follow-up. The difference between assessment with and without thin-layer preparations with regard to diagnostic yield and diagnostic accuracy is then calculated.

Study objective

We hypothesize that diagnostic accuracy increases when, apart from cytologic samples, material is aspirated for thin layer preparation in endoscopic-ultrasound guided fine needle aspiration (EUS-FNA) of masses.

Study design

Baseline: Patient characteristics

6 months after EUSFNA: final diagnosis

Intervention

No intervention is part of this study

Contacts

Public

P.O. box 85500
University Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Scientific

P.O. box 85500
University Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
W.F.W. Kappelle
Utrecht 3508 GA
The Netherlands
+31 (0)88 5750724

Eligibility criteria

Inclusion criteria

-EUS-FNA of a mediastinal/ abdominal mass

-Written informed consent

Exclusion criteria

-Failure to acquire material during EUS-FNA.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-11-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-11-2014
Application type:	First submission

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
NTR-new	NL4761
NTR-old	NTR4889
Other	Ethical committee Utrecht : 14-496

Study results