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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29425

Bron
NTR

Verkorte titel
The Cytolyt study

Aandoening

EUS-FNA of a mass

endo-echografie van een massa

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline: Patient characteristics

6 months after EUSFNA: final diagnosis

Onderzoeksproduct en/of interventie

No intervention is part of this study

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-EUS-FNA of a mediastinal/ abdominal mass

-Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Failure to acquire material during EUS-FNA.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-11-2014
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-11-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4761
NTR-old	NTR4889
Ander register	Ethical committee Utrecht : 14-496

Resultaten