Rapid on-site evaluation vs. randomly collected samples from mediastinal and abdominal lymph nodes obtained by endoscopic ultrasound-guided fine-needle-aspiration

Gepubliceerd: 03-11-2014 Laatst bijgewerkt: 18-08-2022

The hypothesis is that rapid on-site evaluation increases diagnostic accuracy of EUS-FNA aof lymph nodes

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23056

Bron
NTR

Verkorte titel
ROSE-study

Aandoening

lymphadenopathy

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

the percentage of cases in which the local cytopathologist correctly diagnosed the lymph node, based on the EUS-FNA samples of the lymph node

Toelichting onderzoek

Achtergrond van het onderzoek

Endoscopic ultrasound guided fine-needle aspiration (EUS-FNA) of lymph nodes is an important diagnostic instrument for an increasing number of disorders. A representative sample of the lymph node is essential for making a diagnosis. Therefore, there is an ongoing ambition to improve the diagnostic accuracy of EUS-FNA. Rapid on-site evaluation (ROSE), with a cytotechnician or cytopathologist on-site, is an option to achieve this. However, the additional value of ROSE with regard to lymph nodes has never been studied in a randomized controlled trial. We hypothesize that ROSE increases the diagnostic accuracy of EUS-FNA of mediastinal and abdominal lymph nodes when compared to random “blind” FNA.

Doel van het onderzoek

The hypothesis is that rapid on-site evaluation increases diagnostic accuracy of EUS-FNA aof lymph nodes

Onderzoeksopzet

Baseline: patient characteristics

1 week after procedure: (severe) adverse events

1 month after procedure: (severe) adverse events

6 months after procedure: Final diagnosis is determined

Onderzoeksproduct en/of interventie

patients who gave informed consent in who EUS-FNA of a mediastinal/abdominal lymph node is performed are randomized to rapid on-site evaluation after each pass or to 'Random', in which case 5 passes are done before the cyto-technician informs the endosonographer whether the samples are adequate. This way, a situation in which the technician is not in the room is simulated. At a later time, all samples are reviewed by a dedicated pathologist.

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
University Medical Center Utrecht
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)

-≥18 years old

-EUS with FNA of a lymph node in either the mediastinum or abdomen

-Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Patients with a poor mental condition or mental retardation, unable to understand the nature and consequences of the study

-Coagulopathy (INR>1.5, platelets<50.000/mm3) which has not been corrected prior to the procedure

-Pregnancy

-Previous participation in the ROSE study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-02-2014
Aantal proefpersonen:	234
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	NL4748
NTR-old	NTR4876
Ander register	Ethical committee Utrecht : 13-455

Resultaten