IMproving genomic Profiling and Reducing time to Oncological treatment and Validating the use of EUS-B in Diagnosing lung cancer (IMPROVED)

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Background

In recent years, an increased number of treatments targeting genomic changes in NSCLC (Non-small cell lung cancer) have been introduced in the field of oncology, thus increasing the demand for better tissue acquisition in order to perform successful genomic analyses.

EUS-B (endoscopic ultrasound via the esophagus) is a safe and relatively new technique that allows the pulmonologist to reach structures that otherwise cannot be reached by conventional bronchoscopy or EBUS. New needles have been developed to optimize the diagnostic yield of tissue biopsies.

The amount of circulating tumor DNA (ctDNA) can be measured in blood samples (liquid biopsies), which holds a promising potential to obtain important molecular information without performing a tissue biopsy.

Aim

The overall aim is to shorten time to onset of optimal treatment both in patients with suspected lung cancer and in patients with suspected recurrence/progression of NSCLC.

Studies

This project consists of 3 multicenter studies (Næstved, Roskilde and Odense) with focus on an improved patient-friendly diagnosis of lung cancer, which reduces time-to-treatment.

Study 1 includes 280 patients referred with suspected lung cancer and with indication of EUS-B. Patients will be randomized to either conventional FNA needle or the novel “crown-cut” FNB needle. Primary outcome will be a comparison of the ability to provide a successful NGS analysis.

Study 2 includes 126 patients referred with suspected progression or recurrence of a previously treated NSCLC, and with indication for EUS-B or EBUS. Patients are randomized to FNA vs FNB as in study 1, and with the same primary outcome.

Study 3: Before endoscopy, a blood sample will be taken from the patients in study 2, and analyzed for circulating tumor DNA (ctDNA) for NGS. The purpose is to explore the added diagnostic value of ctDNA in NSCLC recurrence/progression as well as comparing the genomic profile measured by ctDNA with that of tissue samples: can ctDNA make tissue biopsies redundant when diagnosing recurrence/progression of a known NSCLC?