VALUE OF DANISH STANDARDS OF CARE AND PLEURAL FLUID-TUMOR-DNA IN WORK-UP AND TREATMENT OF MALIGNANT PLEURAL EFFUSION (OPTIMIZE-pleura)

The aim of OPTIMIZE-pleura, a National study, is to investigate if the development and implementation of Danish standards on work-up and treatment of malignant pleural effusion (MPE) results in shorter time to diagnosis and treatment, and thus positively impacts the life of affected patients. In parallel, we will investigate if measurement of free tumor-DNA (ctDNA) in pleural fluid increases diagnostic accuracy and thus time to diagnosis.

Lung cancer is a common cause of MPE, which is associated with 8 months survival, considerable symptoms burden, and significant costs related to MPE drainage and hospitalization. In Denmark, approximately 5,000 persons are diagnosed with MPE annually – the majority caused by lung cancer. At least twice as many are suspected of MPE, and the uncertainty during work-up is associated with emotional instability due to the poor prognosis of MPE.

Preliminary reports suggest that work-up and care of MPE at Danish hospitals are both heterogeneous, and do not live up to international standards, resulting in prolonged time to diagnosis and treatment. Measurement of pleural fluid ct-DNA is in small, single-center studies shown to improve diagnostic accuracy.

Recommended standard procedure of patients with recurrent pleural effusion comprises blood sampling, pleural tap and chest CT. Guidelines also recommend that patients with MPE are early offered definitive pleural interventions (indwelling pleural catheter, pleurodesis) to reduce MPE disease burden.

We aim to investigate if Danish level of MPE care is improved by development and implementation of Danish standards of MPE care. Danish standards are needed in adjunct to international guidelines, as Danish clinicians have access to diagnostic techniques that presently are not included in guidelines. In addition, we aim to investigate the added diagnostic value to standard work-up of routine-analysis of pleural fluid ctDNA.

Danish standards of care will be developed in a National collaboration between experts – including co-authors of the international guidelines – and patient representatives. Implementation of the developed standards will occur in collaboration between University of Southern Denmark, study group, and both clinicians and head of administration from each involved department. Measurement of pleural fluid ctDNA will be performed at the Department of Pathology, Zealand University Hospital, Denmark, using standard lung cancer DNA-panels.

We plan to include a total of 500 patients from the 14 Danish pleural care centers (250 patients with recurrent pleural effusion of unknown cause, and 250 patients with MPE).

The study is supprted by the participating departments, Danish Research Centre for Lung Cancer, and the National CancerPlan 4 (Kræftplan IV).