Early detection of lung cancer by blood samples

- A prospective observational study

PhD student Sara Witting Christensen Wen
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PhD project

- DETECT: Early detection of lung cancer in patients from general practice
- PROMIL: Prognostic impact of circulating tumor DNA in patients operated for NSCLC
- CIMPRIL: Prognostic impact of circulating tumor DNA in patients receiving radiotherapy with curative intent for NSCLC
- NK Check: Prognostic impact of NK cell activity in patients with NSCLC receiving immunotherapy.

Introduction

- CT scans are a sensitive, but not very specific method for early detection of lung cancer
- Tissue sample is needed for diagnosis – involving risks for the patient
- ”Liquid biopsy” as a method for early detection – we need more specific markers!

Introduction

- Which marker? Mutations, methylations, miRNA, immunology, protein markers etc.?
- Which sample? Blood, sputum, bronchial lavage fluid or…?

- Methylated HOXA9
- NK cell activity

Objectives

- To investigate the diagnostic sensitivity and specificity of the following markers in lung cancer individually and combined:

1. Methylated HOXA9 in plasma and BALF
1. NK cell activity in plasma and BALF
2. Auto-antibodies in plasma and BALF
3. Cancer antigen 125 [CA125], carcinoembryonic antigen [CEA], cytokeratin-19 fragment [CYFRA 21-1], and the precursor form of surfactant protein B [Pro-SFTPB],
4. Breath condensate measuring tumor mRNA by the Hawkeye system

- To investigate the additive diagnostic value of the same markers during follow-up of patients with clinical suspicion of lung cancer
- To investigate the lead-time between changes in plasma markers and lung cancer diagnosis in patients with an ambiguous lesion

Hypotheses

- Detection of abovementioned biomarkers has diagnostic value in patients examined for lung cancer, and there is an additive effect of testing both blood and BALF.
- The blood test has a higher sensitivity and specificity than CT scanning.
- A blood sample analysed for these parameters can be used to risk stratify patients with an ambiguous lesion on a CT scan. [L SEP]

Inclusion and exclusion

Inclusion criteria

- Examination for lung cancer
- Age > 18 years
- Written and orally informed consent

Exclusion criteria

- Previous lung cancer diagnosis
- Other malignant disease within 5 years prior to study enrolment, except basocellular or squamous skin cancer and carcinoma in situ cervicis uteri
- Severe comorbidity making the patient unable to complete the planned follow-up period

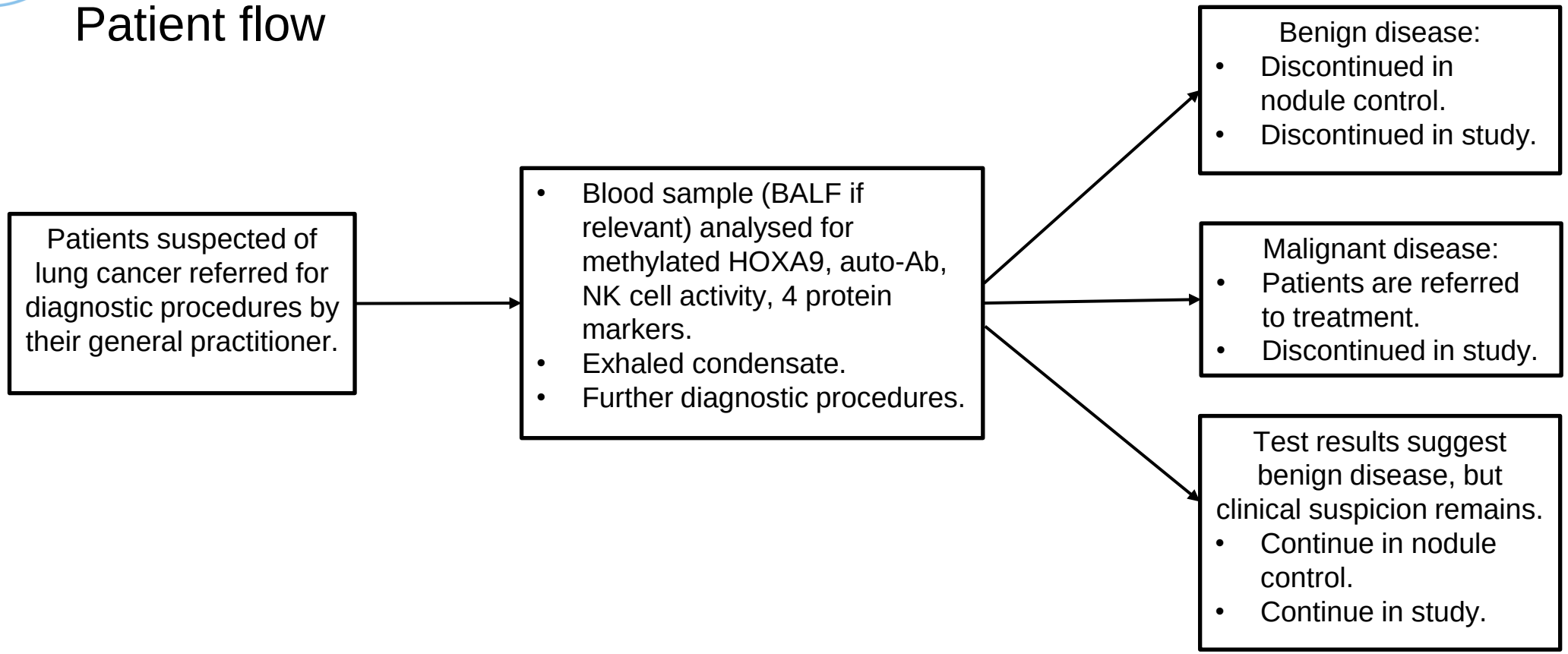
Study design

- Design: Prospective observational study
- Planned number of participants: 250
- End points:

1. Diagnosis of lung cancer initially or during follow up
2. Overall survival

- Enrolment period: August 2018 – January 2020
- Follow up: February 2020 – January 2021

Patient flow



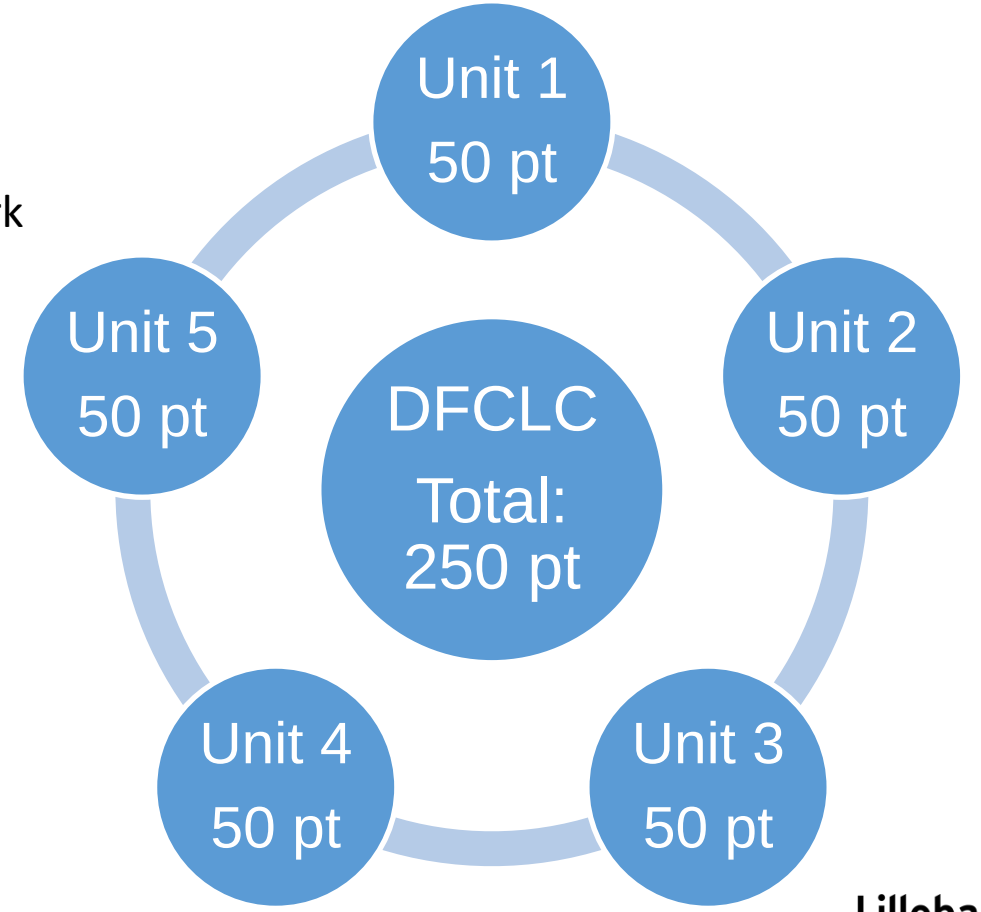
Status November 2019

- Patients enrolled: 150.
- Initial diagnosis of lung cancer: 20-25%.

- Preliminary results presented at ASCO 2019
- Methylated HOXA9 in bronchial lavage fluid as a diagnostic marker
- Sensitivity 75%, specificity 93,9% (n=89)

DETECT-DK: National, prospective observational study

- National multi-center study
- Patients included in the diagnostic centers in Denmark
- 50 patients per participating unit



Thank you

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Questions?

E-mail: sara.christensen@rsyd.dk