Validation of a Prognostic Profile of Non Small Cell Lung Cancer in biopsies, PulmoPrint

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Comparison of micro arrays from biopsy material and surgical specimen for the 72 geneprognostic profile of non-small cell lung cancer.

Ethical review	-
Status	Will not start
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON33429

Source ToetsingOnline

Brief title PulmoPrint in bronchial biopsies

Condition

• Respiratory and mediastinal neoplasms malignant and unspecified

Synonym

lung cancer, Non-small cell lung carcinoma

Research involving Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis **Source(s) of monetary or material Support:** CTMM

Intervention

Keyword: Micro-array, Non-small cell lung carcinoma, Prognostic profile

Outcome measures

Primary outcome

Can the prognosis profile (or other genomic profiles) be performed on biopsy material (feasibility) and is the gene expression in the biopsy sample comparable to the expression in the surgical specimen?

Secondary outcome

- What percentage of mismatch is due to heterogeneity within the tumor?
- What percentage of biopsies has too little (less than 30%) or no cancer cells

as assessed by H&E staining?

- To what degree correlate the results from biopsy with the results from

surgical specimen based on microarray results as well as IHC markers?

Study description

Background summary

Current staging methods are imprecise for predicting the outcome of treatment of non*small cell lung cancer (NSCLC). In previous research we used whole-genome gene expression micro arrays to analyze frozen-tumor samples from 103 patients (pT1&2, N0&1, MO), who had undergone complete surgical resection in 5 European institutions. The developed 72-gene prognostic profile can identify early stage NSCLC patients with a low-risk for disease recurrence within three years after initial diagnosis.

However, for the full validation of a prognostic test, additional validation studies are required. Additionally, for the use in clinical routine, the prognostic test has to be adapted to a robust and standardized test with stringent quality controls. Previously the prognostic profile has been analyzed from frozen resection specimens, which are not widely available. Besides that, diagnostically it would be an addition to be able to use the prognostic profile on smaller biopsies, before performing a resection.

Study objective

Comparison of micro arrays from biopsy material and surgical specimen for the 72 gene- prognostic profile of non-small cell lung cancer.

Study design

Prospective study to compare the prognosis profile results from biopsy material taken before surgery with surgical material from the same patient with NSCLC. 25 patients will be included. Of 5 patients 6 samples will be obtained from the surgical resection material, from the following 20 patients both pre- and peroperative samples will be obtained.

Study burden and risks

Biopsies will be taken during routine examination and treatment, which minimizes the burden for the patient to a small extent. No additional risks are expected. There will be no direct benefit for indivudual patients. After complete validation of PulmoPrint has taken place benefit can be axpected for a larger group of NSCLC patients stage I or II.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- 1. Patients with stage I or II of NSCLC who will undergo a resection
- 2. All histological subtypes of NSCLC
- 3. signed Informed consent

Exclusion criteria

- 1. Prior radiotherapy to target tumor
- 2. neo adjuvant treatment

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	15
Туре:	Anticipated

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Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO

ID NL27970.031.09