# Characterization of Methylation Patterns in Lung Cancer (Lung-RND-001)

Published: 12-05-2017
Last updated: 20-06-2024

• Characterization of methylation patterns in blood samples and finding of methylation patterns that are unique to lung cancer.• Development of a molecular test for early diagnosis of lung cancer from a blood sample that will be more sensitive and...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Respiratory and mediastinal neoplasms malignant and unspecified |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON45678

**Source**
ToetsingOnline

**Brief title**
Lung-RND-001

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

**Synonym**
lung cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Nucleix Ltd.
**Source(s) of monetary or material Support:** Nucleix Ltd.

## Intervention

**Keyword:** Lung Cancer, Methylation, Nucleix

## Outcome measures

### Primary outcome

Methylation patterns that are unique to lung cancer.

### Secondary outcome

None

# Study description

### Background summary

The aim of this study is to find methylation patterns that are unique to lung cancer and to develop a blood test for early diagnosis of lung cancer based on methylation biomarkers.

### Study objective

• Characterization of methylation patterns in blood samples and finding of methylation patterns that are unique to lung cancer.
• Development of a molecular test for early diagnosis of lung cancer from a blood sample that will be more sensitive and specific than existing tests.

### Study design

Single blood draw of 30 ml in 1000 subjects from the test group and 1000 subjects from the control group.

### Intervention

Single blood draw of 30 ml.

### Study burden and risks

Single blood draw of 30 ml.

# Contacts

**Public**
Nucleix Ltd.

Pekeris Street 3
Rehovot 7670203
IL
**Scientific**
Nucleix Ltd.

Pekeris Street 3
Rehovot 7670203
IL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Males and females
Test group: subjects18 years and above with a suspicion of a cancerous tumor in the lungs or patients who have already been diagnosed with lung cancer, however did not yet undergo surgery and did not yet receive any treatment for the cancer (including, but not limited to chemotherapy and/or radiation).
Control group: Smokers (currently or in the past) 50 years and above without cancer (current or previous) with preference to subjects which also diagnosed with COPD.

## Exclusion criteria

Test group: Subjects with cancer or history of cancer from any kind (besides lung cancer).

Control group: Subjects with cancer or history of cancer from any kind.

# Study design

## Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 06-07-2017 |
| Enrollment: | 200 |
| Type: | Actual |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 12-05-2017 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | ID |
| --- | --- |
| CCMO | NL61024.100.17 |