MicroRNA profiles in blood and urine in lung cancer: a pilot study

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The primary objective of this study is to compare the profile of MicroRNA*s in the urine and blood of lung cancer patients with the profile of MicroRNA*s in the urine and blood of non-lung cancer patients with similar symptoms and with that of...

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

Summary

ID

NL-OMON46585

Source
ToetsingOnline

Brief title
MicroRNA profiles in blood and urine in lung cancer

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lungcancer

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Pioneers in health care innovation fund

Intervention

Keyword: big data, early diagnostics, lung cancer, microRNA

Outcome measures

Primary outcome

The main study parameters are microRNA sequencing data (read-counts per microRNA) derived from next generation sequencing of the small RNA fractions of blood and urine. The sequencing data will be correlated to clinical parameters:
diagnosed with lung cancer (CT, histopathology), suspected of having lung cancer but not diagnosed (CT, possibly histopathology),
not-suspected of lung cancer or any other disease.

Secondary outcome

Measurements of volatile organic compounds (VOCs) resulting from the electronic nose technology. With the primary outcomes and the secondary outcomes a predictive model will be developed to predict the probability for having lung cancer.

Study description

Background summary

microRNAs regulate the expression of multiple genes to control cellular processes. They are generally involved in maintaining homeostasis. There are ~2500 microRNAs and their expression profile changes with the onset of disease. For instance specific microRNAs are higher or lower expressed in specific types of tumors, dilated hearts and activated immune cells. MicroRNAs are secreted by cells into the circulation and disease-associated microRNAs can thus be found in body fluids such as blood and urine. Based on these facts, it is our hypothesis that the microRNA profiles in blood and urine can be used as

a personalized monitoring system of health to detect the presence of lung cancer.

Study objective

The primary objective of this study is to compare the profile of MicroRNA*s in the urine and blood of lung cancer patients with the profile of MicroRNA*s in the urine and blood of non-lung cancer patients with similar symptoms and with that of healthy volunteers.

Key questions to be answered by this study are:
-> Can lung Can lung cancer- associated microRNAs can be found at elevated levels in the urine of patients?
-> Are lung cancer-associated microRNA profiles in urine similar to lung cancer-associated microRNA profiles in blood?
-> Are urine and/or blood reliable sources of microRNAs for the diagnosis of lung cancer. Which of the microRNA profiles (blood or urine) has the better diagnostic value.

Study design

Pilot study in maximal 75 patients suspected of lung cancer and 25 healthy volunteers.

Study burden and risks

Volunteers are asked to collect one urine sample (50ml) and one blood sample of 10 ml. There are no known risks
associated with urine collection. There are some known risks or adverse effects to blood sample collection like
hematoma which can cause discomfort and pain. The overall burden for subjects is considered low in this study.

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

maximal 75 patients with a suspicion of lung cancer (in order to obtain 25 patients with lungcancer stage 3 / 4 and 25 patients with a negative diagnosis)
- between 45-80 years of age

Exclusion criteria

Patients; known other than lung cancer malignity, urinary tract infection
Controls: known other than lung cancer malignity, no suspicion of lung cancer malignicy, pneumonia, urinary tract infection

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):	18-07-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2018
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL64386.044.18