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In vivo isolation of circulating tumor cells from peripheral blood of patients with lung cancer by using a structured antibody-coated nanodetector

Submission date
23/01/2012

Recruitment status
No longer recruiting

Registration date
06/02/2012

Overall study status
Completed

Last Edited
06/02/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and aims
Lung cancer is the most prevalent cancer and the major cause of cancer-related death worldwide. To detect this kind of cancer in very early stages, modern radiological diagnostic methods are used. An important part is the monitoring of the patients after cancer treatment, and to predict the outcome of the disease, especially the early detection of local recurrence (cancer coming back) and distant metastases (spread of cancer to other parts of body). The goal of our research is the identification of the disease and monitoring of patients after treatment. We want to evaluate with this study the safety and the functionality of a medical device, which is able to isolate circulating cancer cells from the bloodstream. A thin wire, also called nanodetector, is inserted into the bloodstream. The nanodetector has a special coating which has the ability to bind to cancer cells and thus to estimate the number of circulating tumor cells. This method has the advantage of identifying tumor cells in a much larger volume than a standard blood sample taken out of the body.

Who can participate?
You are 18 years or older with lung cancer and you have not undergone surgery yet

What does the study involve?
If you take part in the study, first of all, you will be asked to give a small sample of blood to test blood values for inclusion and exclusion into the study. Should you be eligible to participate the nanodetector will be inserted in the vein. The procedure of inserting the nanodetector is similar to inserting a small tube for blood collection and takes 30 min. This is a standard procedure in hospitals and medical practices. All patients in the study were treated in the same way. Afterwards you will be asked again to give a small sample of blood to check if blood values change after the insertion of the nanodetector.

What are the possible benefits and risks of participating?
The cancer patients participating benefit from increased regular medical care, ranging from the

provision of additional, non-routine blood tests.
The procedure is similar to a normal blood collection. Therefore the risk for the participants is comparable to the risk of a normal blood collection. All insertions of the nanodetector will be carried out by trained physicians.

Where is the study run from?
The study takes place at the Medical University in Poznan, Clinic for Thoracic Surgery, Poland

When is study starting and how long is it expected to run for?
Patients have been enrolled since March 2010, and the study will end in March 2012. Until that time 60 subjects should be enrolled.

Who is funding the study?
The study is being funded by the GILUPI company (Potsdam, Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CIP FSMW EpCAM-Lunge-P000

Study information

Scientific Title

In vivo isolation of circulating tumor cells from peripheral blood of patients with lung cancer by using a structured antibody-coated nanodetector: An explorative mono-center non-randomized blinded trial

Study objectives
The aim of this explorative mono-centre trial is the in vivo proof of concept. The compatibility in patients with operable lung cancer after exposure of the nanodetector in the patient vein for 30 minutes will be tested. Besides of that a performance analysis will be done. In a second group of patients with operable lung cancer a double application of the nanodetector will be performed to assess the reliability of the nanodetector after positive evaluation of the proof of concept. The specificity of the device will be tested by the inclusion of a control group (non-cancer patients). The analysis of the applied nanodetectors will be done under blinded conditions. In parallel the CellSearch system, using a similar antibody-based extraction technique for circulating tumor cells in a single blood sample in vitro, will be used as a reference system. Furthermore the CEER-Assay (Prometheus Labs) will be used for an explorative analysis of certain tumor relevant protein pathways on the isolated CTCs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Committee on Bioethics at the Medical University, Charles Marcinkowski in Poznan approved on the 04th of March 2010 (Uchwala nr 48/10) the clinical investigation protocol
The amendment to protocol 05 approved on the 17th of June 2010 (KB nr 574/10)
The amendment to protocol 07 approved on the 08th of September 2011 (Uchwala nr 764/11)

Study design
Explorative mono-center blinded trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Lung cancer (non small cell lung cancer - NSCLC, stage I-IV)

Interventions
The first group of participants will receive a single application of the nanodetector. This set of subjects is the blinded part of the study. Non-cancer and lung cancer patients will be included in

the study. After the complete recruitment of this group of subjects a second group (only cancer patients) will be included in the study.

In the second group of participants two nanodetectors will be applied under same conditions. The nanodetector will be inserted pre-operatively. Each nanodetector will be inserted in an arm vein for 30 min. To demonstrate the functionality of the nanodetector, circulating tumor cells will be detected by immunocytochemistry. In parallel a blood sample will be taken from every patient before the application of the nanodetector. This blood sample will be analyzed with the CellSearch® method. The CellSearch® method (method with FDA-approval) acts as a reference system. At the end the data from these two methods will be compared.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Positive isolation of circulating tumor cells from peripheral blood of patients with lung cancer by using the nanodetector (proof of concept)
2. Demonstration of good biocompatibility and safety
3. Investigation of the specificity of the device

Secondary outcome measures
1. Assessment of the accuracy of the nanodetector
2. Review of product-application-procedures
3. Comparison of the results with the CellSearch® method
4. Explorative analysis of cancer related cell pathway proteins by using the CEER-Assay (Prometheus Labs)

Overall study start date
23/03/2010

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Subjects suffering from lung cancer (diagnosed), they are qualified for radical operation of the tumor
2. Age ≤ 18 years
3. Results of laboratory tests are in the area that the patient is qualified to perform an operation
4. Written informed consent
5. For control group: Five subjects are non-cancer patients

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Medical history revealing psychiatric disease or any other serious diseases
2. Participating in other clinical trials
3. Any findings in physical examination that would in the opinion of the investigator make participation unsafe for the volunteer
4. Any presence or history of allergy (including hay fever)
5. Any history of anaphylactic or anaphylactoid
6. Auto immunological diseases: Anti-phospholipid antibody syndrome (lupus anticoagulant), Goodpasture's syndrome, lupus erythematosus, relapsing polychondritis, rheumatoid arthritis, sarcoidosis, scleroderma, Sjogren's syndrome, antineutrophilic cytoplasmic antibody (ANCA)
7. Immuno deficiencies: X-linked aggamaglobulinaemia (XLA), severe combined immunodeficiency (SCID), common variable immunodeficiency (CVID), selective IgA deficiency
8. Known infection with: hepatitis A, B and C, human immunodeficiency virus (HIV), herpes simplex virus (HSV), cytomegalovirus (CMV), syphilis, toxoplasmosis, tuberculosis; known illegal drug abuse
9. Changes in laboratory values with negative performance for surgery
10. Signs of inflammation reactions

Date of first enrolment
23/03/2010

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
Poland

Study participating centre
Uniwersytet Medyczny w Poznaniu
Poznan
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Sponsor information

Organisation
GILUPI GmbH (Germany)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
GILUPI GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration