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99mTc-3PRGD2 SPECT/CT for response evaluation of lung cancer

Submission date	Recruitment status	[ ] Prospectively registered
20/01/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/02/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/11/2017	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Integrin αβ3 is a receptor that is found on various types of tumor cell but not on (or very low on) normal cells. Therefore, it is becoming a valuable target for the diagnosis of tumors and monitoring the effects of treatment. Arginine-glycine-aspartic acid (RGD) can specifically bind to the integrin αβ3 receptor. A variety of radioactively labeled (radiolabeled) RGD-based peptides have been developed for detecting integrin avb3 by positron emission tomography (PET) or single photon emission computed tomography (SPECT) scans. Among all the RGD radiotracers studied, 18F-Galacto-RGD and 18F-AH111585 have been well investigated and the results demonstrated that both radiotracers could be used to detect various types of tumors. Recently, new 99mTc-labeled RGD dimeric peptides have showed much higher binding to integrin avb3 and increased tumor uptake. 99mTc-3PRGD2 has been tested in lung cancer patients, appeared to be useful for diagnosis, and no side effects have been observed to date. The aim of this study is to assess the effectiveness of 99mTc-3PRGD2 for evaluating the early response of lung cancer to treatment.

Who can participate?
Patients aged 30 to 70 with lung cancer who are undergoing chemotherapy and/or molecular targeted treatment for at least 3 cycles or 3 months without radiotherapy

What does the study involve?
The study involves three 99mTc-3PRGD2 SPECT/CT scans at the start of the study, after one cycle, and after three cycles of treatment, respectively. An early evaluation after one cycle of therapy is compared with a standard evaluation after three cycles, and the new method is compared with CT and 18F-FDG PET/CT scans for evaluation.

What are the possible benefits and risks of participating?
Participants receive free 99mTc-3PRGD2 SPECT/CT scans and detailed medical follow-up. Participants are exposed to radiation from the low-dose CT and radiotracers. Possible side effects to the tracer 99mTc-3PRGD2 may occur, although no side effects have been observed to date.

Where is the study run from?
Peking Union Medical College Hospital (China)

When is the study starting and how long is it expected to run for?
February 2012 to February 2013

Who is funding the study?
1. Capital Special Project (China)
2. National Natural Science Foundation (China)
3. Ministry of Science and Technology (China)

Who is the main contact?
Prof. Fang Li

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2012-01

Study information

Scientific Title
A multicenter clinical study of 99mTc-3PRGD2 SPECT/CT in an early response evaluation of lung cancer to chemotherapy and molecular-targeted therapy

Study objectives
A group of clinically diagnosed lung cancer patients by 99mTc-3PRGD2 SPECT/CT and 18F-FDG PET/CT before treatment, treatment of early and late after the end of treatment or imaging to monitor tumor, treatment effect. According to PERICST standard in the evaluation of therapeutic effect.

The aim of this study is to compare 99mTc-3PRGD2 SPECT / CT with 18F-FDG PET/CT for response evaluation of lung cancer. The latter generally used PET Response Criteria in Solid Tumors (PERCIST) for response evaluation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Peking Union Medical College Hospital, 16/11/2010, ref: S336

Study design
Prospective study design

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Lung cancer

Interventions
Single treatment arm will be used. Methodology: 99mTc-3PRGD2 SPECT/CT scans.
This is a diagnostic, single group assignment, open label efficacy study. Three 99mTc-3PRGD2 SPECT/CT scans will be performed at baseline, post one cycle, and post 3 cycles of treatment, respectively for each patient. 99mTc-3PRGD2 will be intravenously injected 40 minutes before each scan. The dose is 0.3 mCi/kg body weight (± 5%). Follow-ups will be performed every 3 months until the end of the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Changes of 99mTc-3PRGD2 uptake after one cycle of therapy compared to that after three cycles
2. Determine if the early uptake changes of 99mTc-3PRGD2 after one cycle of therapy compared to the baseline can reflect that of three cycles later

Key secondary outcome(s))
1. Changes of 99mTc-3PRGD2 uptake compared to those of CT and/or PET/CT
2. Determine if the 99mTc-3PRGD2 evaluations either post one cycle or post three cycles of treatment is better than or comparable to those of CT according to the RECIST criteria and/or PET/CT evaluations using PERCIST criteria

Completion date
01/02/2013

Eligibility

Key inclusion criteria
1. Age of 30 - 70 years
2. Clinical pathology in patients with lung cancer
3. Patients without radiotherapy
4. Radiation therapy
5. The clinical plan complete regimen in the treatment of patients
6. Can follow up the survival period of patients
7. Can obtain complete evaluation of the efficacy of imaging data before and after treatment
8. Volunteered to participate in and signed informed consent

Clinical diagnosis of pulmonary primary tumor, and without chemotherapy, radiotherapy patients, histologic type is not restricted. Clinical chemotherapy scheme is not restricted. Requirements of each patient in chemotherapy before a week, the first course of chemotherapy after the second chemotherapy was started 1 weeks prior to, and during the first chemotherapy 3 months after the start of the three time points respectively imaging (including CT, MR and / or US control imaging). If the patients during the treatment period replacement therapy must be recorded in detail. Requirements for follow-up each survival in patients with stage.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Withdrawal of informed consent
2. Loss to follow-up
3. Against research programme

Date of first enrolment
01/02/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
China

Study participating centre
Peking Union Medical College Hospital
Beijing
China
100730

Sponsor information

Organisation
National Natural Science Foundation (China)

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
Capital Special Project (China) ref: Z111107058811096

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name

Ministry of Science and Technology of the People's Republic of China (ref: 2009ZX09103-733)

Alternative Name(s)
Chinese Ministry of Science and Technology, Ministry of Science & Technology, People Republic of China, , Ministry of Science and Technology (China), State Science and Technology Commission, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration