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Particle radiotherapy in early stage non-small cell lung cancer

Submission date
10/08/2018

Recruitment status
No longer recruiting

Registration date
14/08/2018

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lung cancer is the leading cause of cancer-based death worldwide. Approximately 80% of patients with lung cancer are diagnosed with non-small cell lung cancer (NSCLC). Currently, the standard therapy for early stage NSCLC is surgery. However, patients who have chronic lung or heart disease may not be able to endure this surgery. Instead, radiation therapy (RT) has become the first choice of treatment for these patients. Most RT uses photon beams, which deliver high doses of radiation to and affect a larger area of normal organs and tissues, which can lead to damage in these areas.
Particle therapy (PT) is an alternative to RT, which can provide various advantages over RT, including better protection of normal organs and tissues, and better tumor control. Therefore, PT can be used for NSCLC patients with impaired lung or heart function. There are 2 major techniques used for PT, called passive scattering (PS) or pencil-beam scanning (PBS). In theory, PBS provides a better dose distribution of therapy (the spread or distribution of the treatment) than PS. However, PBS has been adopted less quickly as a treatment because of possible dose inaccuracies, due to movement of tumors and surrounding normal tissues. Carbon-ion radiation therapy (CIRT) is a type of PT that uses the PBS technique; however, no patient experiences with using this to treat NSCLC have been reported.
This study aims to report the initial experience with and clinical results of a group of patients with early stage NSCLC treated with CIRT PT using PBS, as part of our work to reduce the impact caused by motion and improve the dose distribution accuracy of PBS PT in patients with lung cancer.

Who can participate?
Adult patients with early stage non-small cell lung cancer (NSCLC) treated with particle therapy in Shanghai Proton and Heavy Ion Center (SPHIC)

What does the study involve?
The toxicity and effectiveness of particle therapy was recorded retrospectively from the records of patient's follow-up period after cancer treatment.

What are the possible benefits and risks of participating?
There is no direct participation required from participants, therefore there are no known benefits or risks of participating in this study.

Where is the study run from?
Shanghai Proton and Heavy Ion Center (SPHIC) (China)

When is the study starting and how long is it expected to run for?
July 2014 to July 2018

Who is funding the study?
1. Shanghai Science and Technology Commission (China)
2. Shanghai Shen Kang Hospital Development Center (China)
3. Shanghai Pudong New Area Technology and Economic Commission (China)

Who is the main contact?
Jingfang Mao
jingfang.mao@sphic.org.cn

Contact information

Type(s)
Scientific

Contact name
Dr Jingfang Mao

Contact details
4365 Kang Xing Road
Shanghai
China
201321

Additional identifiers

Protocol serial number
171020EXP-01

Study information

Scientific Title
Early stage non-small cell lung cancer treated with pencil beam scanning particle therapy: retrospective analysis of early results on safety and efficacy

Study objectives
Particle therapy should be effective and safe in treating early stage non-small cell lung cancer based on its dosimetric and radio-biologic advantages.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Research Board (IRB) of the Shanghai Proton and Heavy Ion Center (SPHIC), 27/10/2017, 171020EXP-01

Study design
Observational single-center retrospective study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-small cell lung cancer (NSCLC)

Interventions
All patients were evaluated weekly for treatment-induced toxicities and disease response /progression during their treatment. After the completion of RT, all patients are required to be evaluated according to our institutional follow-up protocol for lung cancer at 3 months after the 1st day of RT, every 3-4 months within the first 2 years, every 6 months between year 3 and 5, and annually thereafter. Treatment-induced side effects were scored using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03, for events observed after the first dose of irradiation. Toxicities occurred 90 or more days after the completion of PRT were defined as late toxicities. All the toxicities were recorded prospectively.
The overall survival (OS) time was calculated from the date of pathological diagnosis of the primary disease or radiological diagnosis of disease for patients without pathological confirmation until death or the date of the last follow-up. The time to local, regional, or distant failure was calculated from the date of the first fraction of PT until documented first considered treatment failure. Local control and various survival rates were calculated using the Kaplan-Meier method.

Intervention Type
Device

Primary outcome(s)
The following were assessed at 3 months after the first day of treatment, then every 3-4 months within the first 2 years, then every 6 months for years 3-5, and annually thereafter:
1. Treatment-induced side effects and toxicities, assessed using the Common Terminology Criteria for Adverse Events (CTCAE) version 4.03
2. Disease response and progression, assessed using the Response Evaluation Criteria in Solid Tumours (RECIST) version 1.1

Key secondary outcome(s))
1. Overall survival time, calculated from the date of pathological diagnosis of the primary disease, or radiological diagnosis of disease for patients without pathological confirmation, until death or the date of the last follow-up
2. TIme to local, regional, or distant failure, calculated from the date of the first fraction of particle therapy until the documented first considered treatment failure
3. Local control and various survival rates, calculated using the Kaplan-Meier method

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Non-small cell lung cancer (NSCLC):
1.1. According to the following criteria of the American Association of Cancer staging version 7:
1.1.1. T1-2 (T1 indicates that the cancer is contained within the lungs and T2 indicates that either the cancer is 3-5 cm in size, or any of the following: the cancer involves the main airway but is not close to where the bronchus divides, the cancer involves the inner lining of the chest cavity, or that part/all of the lung has collapsed or is blocked)
1.1.2. N0-1 (N0 indicates no spread to lymph nodes, N1 indicates there are cancer cells in the lymph nodes)
1.1.3. M0 (no distant cancer spread found)
1.2. Medically inoperable or declined surgery
2. Longest diameters of primary tumour and hilar lymph node <5 cm
3. Pathologically confirmed NSCLC or clinically diagnosed as NSCLC with the Fluorodeoxyglucose-Positron Emission Tomography/Computed Tomography (FDG-PET/CT) avid lung lesion
4. Diagnosed with NSCLC with CT scans by 2 senior radiologists independently

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Locally advanced or metastastic NSCLC at diagnosis
2. Previously received radiotherapy
3. Younger than 14 years of age
4. No signed informed consent

Date of first enrolment
01/08/2014

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
China

Study participating centre
Shanghai proton and heavy ion center
4365 Kang Xing Road
Shanghai
China
201321

Sponsor information

Organisation
Shanghai Proton and Heavy Ion Center

Funder(s)

Funder type
Not defined

Funder Name
Shanghai Science and Technology Commission

Funder Name
Shanghai Shen Kang Hospital Development Center

Funder Name
Shanghai Pudong New Area Technology and Economic Commission

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to privacy protection.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/01/2019		Yes	No