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Cost-effectiveness review of inpatient lung cancer care

Submission date 22/06/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/06/2017	**Overall study status** Completed	
Last Edited 26/11/2020	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Lung cancer is one of the most common cancers worldwide. Routine inpatient care (RIC) for lung cancer consists of a combination of procedures. Each of these procedures not only affects disease outcomes but also incur considerable costs. Due to free selection of hospitals and lack of referral and follow-up mechanisms in China, physicians at individual hospitals cannot link their routine diagnosis and treatment with patients' mid- and long-term outcomes. This study examines RIC for lung cancer patients and explores paths of combinations of RIC procedures and their contributions to patient outcomes taking costs into consideration.

Who can participate?
Patients aged 18 and over with lung cancer, from rural Anhui province, China

What does the study involve?
The participants' medical records from all their inpatient care at different hospitals due to cancer are retrieved. The RIC procedures and their costs are extracted from the records and patient outcomes (e.g., survival time, quality of life) are collected through a follow-up survey.

What are the possible benefits and risks of participating?
The results of this study will help to improve treatment by improving outcomes and/or lowering costs.

Where is the study run from?
Anhui Medical University (China)

When is the study starting and how long is it expected to run for?
July 2017 to June 2019

Who is funding the study?
Anhui Provincial Government (China)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A cost-effectiveness evaluation of routine inpatient care for lung cancer patients in rural Anhui, China: methods and measures

Study objectives
There is a general paucity of and an urgent need for data on the cost-effectiveness of complex combinations of routine inpatient care (RIC) procedures for cancer patients which not only affect disease outcomes but also incur considerable costs. This study examines RIC for lung cancer patients in rural Anhui, China and explores paths of combinations of RIC procedures and their contributions to patient outcomes taking costs into consideration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Anhui Medical University Biomedical Ethics Committee, 23/03/2017, ref: 20170311

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
The study adopts a retrospective cohort study design and proceeds in 5 steps. Step 1 defines 4 main categories of study variables including clinical procedures, direct cost and effectiveness of the procedures, and factors affecting use of the procedures and their cost and effectiveness. Step 2 selects a cohort of 5000 lung cancer patients diagnosed between 01/07/2014 and 30/06/2015 from rural Anhui by clustered randomization. Step 3 retrieves the records of all the inpatient care episodes incurred by the cohort for treating their lung cancer and extracts data about RIC procedures, immediate patient outcomes (e.g., Karnofsky performance status, symptom score, lung function score) and influencing factors (e.g., stage of cancer, age, gender) by two independent researchers using a pre-developed worksheet. Step 4 estimates the direct cost of each of the RIC procedures identified using micro-costing and collects data about long-term patient outcomes (e.g., progression-free survival, quality of life) through a follow-up survey of patients or their relatives. Step 5 analyzes data collected and explores paths of RIC procedures and their relations with patient outcomes, costs and a whole range of clinical and socio-demographic factors using frequency-cost tabulation, procedure-outcome trees, multivariate regression models and others.

Intervention Type
Other

Primary outcome measure
1. Gains in months of survival per unit cost
2. Gains in months of progression-free survival per unit cost
Measured at endpoint of the study, i.e., some 2 to 2.5 years after first diagnosis of lung cancer

Secondary outcome measures
1. Gains in quality of life score per unit cost
2. Gains in Karnofsky Performance status (KPS) per unit cost

3. Per unit cost gains in compiled indices of symptoms (e.g., chronic cough, chest pain, dysphonia, wasting syndrome, fever)
4. Lung functions (e.g., forced vital capacity, forced expiratory volume in one second, TLCO-SB)
5. Imaging findings (e.g., number of nodes identified in the lung, maximum size of the nodes, presence of abnormalities with the mediastinum or hilum, presence of pleura or pericardial effusion)
6. Biological test findings (e.g., value of CEA, CA125, proGRP, SCC, NSE)
7. Complications and comorbidities (e.g., presence of superior vena cava syndrome, superior vena cava syndrome, cerebral thrombosis or cerebral hemorrhage, chronic fibrous pneumonia, pulmonary embolism, cardiac insufficiency, arrhythmi)
Measured at each episode of hospitalization, i.e., at 4 to 6 time points after the first diagnosis of lung cancer depending on actual times of hospitalization due to the lung cancer by individual patients

Overall study start date
01/07/2017

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Lung cancer patients diagnosed between 01/07/2014 and 30/06/2015 from rural Anhui
2. Aged 18 or older

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
5000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/07/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment

China

Study participating centre
Anhui Medical University
Meishan Road 81
Hefei
China
230000

Sponsor information

Organisation
Anhui Medical University

Sponsor details
81 Meishan Road
Hefei
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230032

Sponsor type
University/education

Website
http://www.ahmu.edu.cn

ROR
https://ror.org/03t1yn780

Funder(s)

Funder type
Government

Funder Name
Anhui Provincial Government

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal(s) between 2018 and 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/02/2018	26/11/2020	Yes	No