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Comparison of DWI-MRI and 18F-FDG PET/CT whole body scans in the diagnosis of tumors

Submission date 21/08/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/09/2012	**Overall study status** Completed	
Last Edited 30/03/2017	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims:
There are different types of medical scans that can be used to diagnose tumours (a mass of cells). Diffusion weighted imaging- magnetic resonance imaging (DWI-MRI) is a type of scan that uses the changes of water movement to create an image. 18F-fluorodeoxyglucose Positron Emission Tomography (18F-FDG PET) is a type of scan that uses a small amount of a drug as a tracer (FDG) to show the difference between healthy tissue and diseased tissue. These two different scans show tumour in different ways. Some researchers think DWI-MRI scans can replace 18F-FDG PET scans for diagnosing tumours and that 18F-FDG PET should only be used for certain types of cancers. The aim of this study is to compare different types of imaging to see which one has the best clinical outcomes for diagnosing tumours.

Who can participate?
Adults aged 18-80 who have brain, lung, liver and pancreatic tumour.

What does the study involve?
Participants undergo their standard scan using the 18F-FDG PET/CT scan or the DWI-MRI. Each scan is assessed to see how well it can diagnose tumours.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

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

When is study starting and how long is it expected to run for?
August 2012 to March 2013

Who is funding the study?
Xijing Hospital (China)

Who is the main contact?
Prof Jing Wang
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2012-08-DWI; 2012-08-FDG

Study information

Scientific Title
Comparison of the efficacy of DWI-MRI and 18F-FDG PET/CT whole body scans in the diagnosis of tumors: a multicenter clinical study

Study objectives
DWI (Diffusion weighted imaging, WI) and 18F-FDG PET/CT different imaging mechanism, comparison of DWI-MRI and 18F-FDG PET/CT whole body scan in the diagnosis of tumor efficacy and to find out the best clinical indications. Choice in different city 9 PET/CT center participated in the study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of regsitration

Study design

Prospective randomized blinded controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Brain, lung, liver and pancreatic tumor including T, N and M staging.

Interventions
Injection FDG accoring to mCi/KG. The research focus is to find DWI-MR and FDG PET/CT, as well as how to play their respective advantages in clinical.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. 18F-FDG PET/CT: the number of lesion, SUV
2. DWI-MRI: the number of lesion, ADC

Secondary outcome measures
1. 18F-FDG PET/CT: tumor volume, TLG (suv evolume)
2. DWI-MRI: tumor volume and size (max long axial)

Overall study start date
30/08/2012

Completion date
30/03/2013

Eligibility

Key inclusion criteria
Brain, lung, liver and pancreatic tumor including T, N and M staging.
1. Age of 18 - 80 years

2. Clinical pathology in patients with brain, lung, liver and pancreaticcancer
3. Patients without radiotherapy, chemotherapy
4. DWI and 18F-FDG PET/CT scanning in the same week
5. DWI and 18F-FDG PET/CT scanning sequence is random
6. Volunteered to participate in and signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
More than 150 cases

Key exclusion criteria
1. Withdrawal of informed consent
2. Without pathology result
3. Against research programme

Date of first enrolment
30/08/2012

Date of final enrolment
30/03/2013

Locations

Countries of recruitment
China

Study participating centre
Fourth Military Medical University
Xi'an
China
710032

Sponsor information

Organisation
Fourth Military Medical University (China)

Sponsor details
c/o Prof Jing Wang
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Sponsor type
University/education

Website
http://www.xjhyx.com/

ROR
https://ror.org/00ms48f15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Xijing Hospital (China)

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