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Evaluation of 64-slice Multidetector Computed Tomography (MDCT 64) technique vs Positron emission tomography - computed tomography (PET/CT)

Submission date
22/05/2012

Recruitment status
No longer recruiting

Registration date
03/08/2012

Overall study status
Completed

Last Edited
29/05/2020

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
We are carrying out a study of 300 patients with the three most frequent categories of lymphoma (Hodgkin disease and non-Hodgkin disease [follicular lymphoma and diffuse large B-cell lymphoma]) to compare 64-slice multidetector computed tomography (MDCT 64) and positron emission tomography - computed tomography (PET/CT) in the initial staging of patients. Once the diagnosis is carried out using the assigned technique the most suitable treatment will be decided. This study will provide evidence to recommend the diagnostic technology more suited for each clinical situation. The aim of the economic evaluation is to assess the technologies benefits in relation to the costs in order to use resources efficiently.

Who can participate?
Lymphoma patients aged 18 or over from University Hospital La Princesa, University Hospital La Paz and Clinic University Hospital San Carlos.

What does the study involve?
Patients will be randomly allocated to either MDCT 64 or PET/CT to establish the disease staging and to carry out the lesions study.

What are the possible benefits and risks of participating?
There should be benefits in relation to a better accuracy of disease staging, resulting in a better treatment response. The risk of diagnostic imaging is related to the radiation dose.

Where is the study run from?
The study is led by the Radiodiagnostic Department of La Princesa Hospital in Madrid (Spain).

When is study starting and how long is it expected to run for?
The recruitment started in January 2012. Participants will be enrolled on the study for a period of two years. However, the study will extend beyond with 1-year follow-up of patients.

Who is funding the study?
Funding has been provided by public funds from Health Research Funding (Carlos III Institute).

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
N/A

Study information

Scientific Title
Evaluation of 64-slice Multidetector Computed Tomography (MDCT 64) technique vs PET/CT: A multicenter clinical study of patients with Hodgkin lymphoma, diffuse large B-cell lymphoma and follicular lymphoma

Study objectives
PET/CT hybrid technique provides major accuracy in the initial staging and better precision in the extension study with regards to MDCT 64

Ethics approval required
Old ethics approval format

Ethics approval(s)

Foundation´s Research Committee of La Princesa Hospital and Clinical Research Ethics Committee of La Princesa Hospital (Madrid), May 2011

Study design
Prospective randomized comparative study. Cost-effectiveness study according to the Markov model to compare the different diagnostic techniques.

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
Hodgkin disease and non-Hodgkin disease (Follicular lymphoma and Diffuse Large B-cell lymphoma)

Interventions
Accuracy diagnostic of both techniques (64-slice Multidetector Computed Tomography (MDCT 64) technique vs Positron emission tomography - computed tomography) and treatment response obtained during the treatment (2nd, 3rd cycle) and at the end of the treatment (6th cycle).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Treatment response
2. Disease free survival rates

Secondary outcome measures
1. Diagnostic test number
2. Hospital stay
3. Unit costs
4. EQ-5D survey

Overall study start date
01/01/2012

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Aged 18 years old or over
2. Patients diagnosed by histology of lymphoid neoplasia
3. No previous lymphoma treatment
4. No previous diagnostic technique of staging
5. Informed consent signed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment
72

Key exclusion criteria
1. Renal failure
2. AIDS infection
3. Granulomatous or inflammatory diseases (tuberculosis, sarcoidosis)
4. Performance status > 3

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Spain

Study participating centre
C/ Diego de León, 62
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Sponsor information

Organisation
Carlos III Institute of Economy and Competitiveness Ministry (Spain)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
La Princesa Hospital Foundation (Spain) ref: PI11/01800

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/10/2018	29/05/2020	Yes	No