

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/05/2020	Condition category Cancer	<input type="checkbox"/> 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?

Dr Nieves Gómez León

ngomezl.hlpr@salud.madrid.org

Contact information

Type(s)

Scientific

Contact name

Dr Nieves Gómez León

Contact details

C/ Diego de León, 62

Madrid

Spain

28006

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ngomezl.hlpr@salud.madrid.org

Additional identifiers

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

1. Treatment response
2. Disease free survival rates

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Madrid

Spain

28006

Sponsor information**Organisation**

Carlos III Institute of Economy and Competitiveness Ministry (Spain)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

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

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes