# A pilot study to investigate how best to integrate a PET-CT scan into the radiotherapy planning pathway for lymphoma

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
22/06/2016		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/06/2016	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
10/07/2023	Cancer			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Robin Prestwich

#### Contact details

Level 4 Bexley Wing St. James's Institute of Oncology Beckett Street Leeds United Kingdom LS9 7TF

#### Additional identifiers

**Protocol serial number** RD12/10519

# Study information

#### Scientific Title

A pilot study to optimise the use of FDG PET-CT and deformable image co-registration for lymphoma radiotherapy planning

#### **Study objectives**

Study aim is to evaluate the impact of pre-chemotherapy PET-CT performed in the radiotherapy treatment position upon the accuracy of subsequent radiotherapy target volume definition

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

NRES Committee Yorkshire & The Humber - Leeds East, 24/05/2013, ref: 13/YH/0139

#### Study design

Single centre non-randomised interventional pilot study

#### Primary study design

Interventional

#### Study type(s)

Other

#### Health condition(s) or problem(s) studied

High grade lymphoma

#### **Interventions**

The study aims to recruit up to 20 patients with early stage Hodgkin lymphoma or high grade non-Hodgkin lymphoma. A routine staging PET-CT will be followed at the same session by a PET-CT in the radiotherapy treatment position appropriate radiotherapy immobilisation devices.

Participation in the study will not affect treatment decisions or the radiotherapy planning process. The process of planning radiotherapy will not be systematically altered by the study.

#### Intervention Type

Device

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

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#### Primary outcome(s)

The impact of pre-chemotherapy PET-CT performed in the radiotherapy treatment position upon the subsequent radiotherapy target volume on retrospective analysis. (This will not alter routine treatment for participants). This endpoint will be evaluated using methods of positional analysis to compare radiotherapy target volumes that are constructed with and without the benefit of the PET-CT acquired in the radiotherapy position.

#### Key secondary outcome(s))

To assess the accuracy of image coregistration between pre-chemotherapy PET-CT and the post-chemotherapy planning CT scan.

#### Completion date

31/12/2017

# Eligibility

#### Key inclusion criteria

- 1. Age ≥18 years
- 2. WHO Performance status 0-2 (Appendix A)
- 3. Histologically proven Hodgkin lymphoma or high grade non-Hodgkin lymphoma
- 4. Ann Arbor Stage I/II disease based upon clinical examination and any radiology investigations performed
- 5. Clinical decision to proceed with sequential chemotherapy and radiotherapy if stage I/II disease is confirmed on subsequent PET-CT staging
- 6. Residual disease in situ after biopsy (either palpable or on any imaging acquired pre-PET-CT)
- 7. Able to provide fully informed written consent
- 8. Able to lie flat for 1 hour
- 9. Not be pregnant or breast feeding. Female patients of childbearing potential must agree to use effective contraception, be surgically sterile, or be post-menopausal

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Total final enrolment

19

#### Key exclusion criteria

- 1. Hypersensitivity to 18Fluorine-FDG
- 2. Hypersensitivity to iodinated contrast media
- 3. Poorly controlled diabetes
- 4. Acute renal failure or moderate renal impairment (estimated glomerular filtration rate < 30 mL/min)
- 5. Uncontrolled pain
- 6. Urinary incontinence
- 7. Female patients must not be pregnant and if of child bearing age using adequate contraception
- 8. Breast feeding
- 9. Serious psychiatric comorbidity

#### Date of first enrolment

12/08/2013

#### Date of final enrolment

31/12/2016

#### Locations

#### Countries of recruitment

**United Kingdom** 

England

#### Study participating centre Leeds Cancer Centre

Beckett Street Leeds United Kingdom LS9 7TF

# Sponsor information

#### Organisation

Leeds Teaching Hospitals NHS Trust

#### **ROR**

https://ror.org/00v4dac24

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

The Leeds Teaching Hospitals Charitable Foundation

### **Results and Publications**

Individual participant data (IPD) sharing plan

# **IPD sharing plan summary** Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/09/2018	10/07/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes