

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

Submission date 22/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/06/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/07/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data

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)

-

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 \geq 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 18 Fluorine-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