

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/01/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

20

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**

England

United Kingdom

Study participating centre

Leeds Cancer Centre

Beckett Street

Leeds

United Kingdom

LS9 7TF

Sponsor information**Organisation**

Leeds Teaching Hospitals NHS Trust

Sponsor details

R&D Department, Leeds Teaching Hospitals NHS Trust
34 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/00v4dac24>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Leeds Teaching Hospitals Charitable Foundation

Results and Publications

Publication and dissemination plan

The main study results will be prepared for presentation and publication in a peer reviewed journal.

Intention to publish date

01/01/2017

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?
HRA research summary			28/06/2023	No	No
Results article		06/09/2018	10/07/2023	Yes	No