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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/06/2016	**Overall study status** Completed	
Last Edited 10/07/2023	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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)
-

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