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Low-dose radiation therapy in treating patients with follicular non-Hodgkin's lymphoma

Submission date 23/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/12/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 05/02/2021	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-radiotherapy-for-people-with-follicular-lymphoma-or-marginal-zone-lymphoma

Study website
http://www.cancer.gov/clinicaltrials/CRUK-FORT

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00310167

Secondary identifying numbers
BRD/05/84

Study information

Scientific Title
A phase III multi-centre randomised controlled trial of low-dose palliative radiotherapy for follicular lymphoma

Acronym
FoRT

Study objectives
The palliative treatment of patients with follicular lymphoma with low dose radiation (4 Gy) can produce results that are equal/similar to that of standard dose radiation (24 Gy).

On 15/02/2011 this trial record was updated. The anticipated end date was extended from 31/10/2010 to 30/09/2011 and the target participant number was reduced from 650 to 540.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Eastern Multicentre Research Ethics Committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Non-Hodgkin's follicular lymphoma

Interventions

Control arm: radiotherapy dosage of 24 Gy administered in 12 fractions
Experimental arm: 4 Gy administered in two consecutive fractions

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Local progression-free interval

Secondary outcome measures
1. Acute toxicity
2. Late toxicity
3. Tumour response
4. Overall survival
5. Health economic assessment

Overall study start date
01/10/2005

Completion date
30/09/2011

Eligibility

Key inclusion criteria
The study population will consist of either male or females over the age of 18 years who are diagnosed with histologically proven follicular lymphoma, for whom palliative radiotherapy has been indicated by virture of tumour bulk or anatomical position.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
540

Total final enrolment
548

Key exclusion criteria
1. Stage 1A disease to be treated radically with radiotherapy
2. Histological sub-types other than follicular non-Hodgkin's lymphoma
3. Predicted prognosis less than 3 months
4. Chemotherapy within 4 weeks of planned radiotherapy

Date of first enrolment
01/10/2005

Date of final enrolment
30/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Cancer Treatment
Middlesex
United Kingdom
HA6 2RN

Sponsor information

Organisation
University College London (UK)

Sponsor details
UCL Biomedicine Research and Development Unit
Hampstead Campus
Rowland Hill Street
London
England
United Kingdom
NW3 2PF

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results				No	Yes
Results article	results	01/04/2014		Yes	No
Results article	5-year follow-up results	01/03/2021	05/02/2021	Yes	No