

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 ☒ 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>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00310167

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Local progression-free interval

Key secondary outcome(s)

1. Acute toxicity
2. Late toxicity

3. Tumour response
4. Overall survival
5. Health economic assessment

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 virtue of tumour bulk or anatomical position.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
University College London (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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2014		Yes	No
Results article	5-year follow-up results	01/03/2021	05/02/2021	Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes