

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

Submission date 23/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/02/2021	Condition category Cancer	<input type="checkbox"/> 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

Prof Peter Hoskin

Contact details

Centre for Cancer Treatment
Mount Vernon Hospital
Rickmansworth Road
Northwood
Middlesex
United Kingdom
HA6 2RN

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 virtue 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