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

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

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

Prof Peter Hoskin

Contact details

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

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

Study design

Randomised controlled trial

Primary study design

Interventional

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 virture of tumour bulk or anatomical position.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

ΔII

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Plain English results</u>				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes