

Short Chemo Radio Immunotherapy in Follicular Lymphoma Trial of Y-90 ibritumomab tiuxetan (Zevalin®) as therapy for first and second relapse in follicular lymphoma

Submission date 14/05/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 10/07/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/07/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-zevalin-and-chemotherapy-for-relapsed-follicular-lymphoma>

Contact information

Type(s)

Scientific

Contact name

Prof Timothy Illidge

Contact details

University of Southampton Clinical Trials Unit
MP 131, Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD
+44 (0)23 8079 5154
kc8@soton.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT00637832

Protocol serial number

Study information

Scientific Title

Short Chemo Radio Immunotherapy in Follicular Lymphoma Trial of Y-90 ibritumomab tiuxetan (Zevalin®) as therapy for first and second relapse in follicular lymphoma

Acronym

SCHRIFT

Study objectives

Chemotherapy plus rituximab combinations (6-8 courses) have consistently demonstrated increased complete response rates and markedly prolonged progression-free survival (PFS) when compared to chemotherapy alone in the first-line and relapse settings in patients with follicular non-Hodgkin's Lymphoma (NHL). However, this protracted duration of therapy can be difficult for many patients and increases the incidence of several cumulative toxicities. Abbreviated treatment regimens that deliver equally high response rates and response duration would therefore be attractive alternatives for patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central Manchester Research Ethics Committee. Date of approval: 07/09/2007

Study design

Open-label, single-arm, non-randomised, prospective, phase 2 study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Follicular lymphoma

Interventions

This is an open-label, single-arm, non-randomised controlled trial.

Weeks 0, 3 and 6: Three cycles of rituximab 375 mg/m² (intravenous [IV]) + chemotherapy (R-Chemo)

Week 9: Rituximab IV 250 mg/m²

Week 10: Rituximab followed by ibritumomab tiuxetan (Zevalin®). Dosage: Rituximab IV 250 mg/m²; for Zevalin®: if platelet count >150 x 10⁹L, Zevalin® at 14.8 MBq/kg, or if platelet count between >100 x 10⁹L and <150 x 10⁹L, dose adjusted Zevalin® at 11.1 MBq/kg)

Total duration of interventions: 10 weeks

Follow-up: Weekly until Week 22, then at various intervals up to 5 years

Please use the following contact details to request a patient information sheet:

Ms Louisa Little
University of Southampton Clinical Trials Unit
MP 131, F Level
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD, UK
Email: lal@soton.ac.uk

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Y-90 ibritumomab tiuxetan (Zevalin®)

Primary outcome(s)

Overall response rate (ORR), including combined complete response (CR) and partial response (PR). Follow-up: Weekly until Week 22, then at various intervals up to 5 years.

Key secondary outcome(s)

1. Time to disease progression
2. Time to next treatment
3. Response duration for the responders
4. Safety of the regimen under investigation

Completion date

20/08/2010

Eligibility

Key inclusion criteria

1. Both males and females. Patients must be aged 18 years or older
2. Patients must have a histologically confirmed CD20 +ve follicular lymphoma
3. Patients with at least one of the following symptoms requiring initiation of treatment (as outlined by the modified British National Lymphoma Investigation [BNLI]/Groupe d'Etude des Lymphomes Folliculaires [GELF] criteria):
 - 3.1. Nodal mass >5 cm in its greater diameter
 - 3.2. B symptoms
 - 3.3. Elevated serum lactate dehydrogenase (LDH) or beta-2-microglobulin
 - 3.4. Involvement of at least 3 nodal sites (each with a diameter greater than 3 cm)
 - 3.5. Symptomatic splenic enlargement
 - 3.6. Compressive syndrome
4. Patients must have an World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status (ECOG-PS) less than or equal to 2 and an anticipated survival of at least 6 months
5. First or second relapse after R-chemo (rituximab plus chemotherapy) regimen or

chemotherapy alone. Relapse must have occurred at least 6 months after an R-Chemo regimen but may have occurred less than 6 months after chemotherapy alone

6. Patients must have adequate renal function (defined as serum creatinine <1.5 times upper limit of normal), hepatic function (defined as total bilirubin <1.5 times upper limit of normal), and hepatic transaminases (defined as aspartate transaminase [AST] <5 times upper limit of normal)

7. Patients must have given written informed consent prior to study entry

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

50

Key exclusion criteria

1. Patients who have received investigational drugs <4 weeks prior to entry or who have not recovered from the toxic effects of such therapy
2. Patients who have received previous radioimmunotherapy
3. Patients with active obstructive hydronephrosis
4. Patients with initial disease bulk greater than 10 cm
5. Patients with central nervous system (CNS) disease
6. Patients with evidence of active infection requiring intravenous antibiotics at the time of study entry
7. Patients with advanced heart disease or other serious illness that would preclude evaluation
8. Patients with large pleural or peritoneal effusions
9. Patients with known HIV infection
10. Known hypersensitivity to murine antibodies or proteins
11. Patients who are pregnant or breast-feeding. Male and female patients must agree to use effective contraception for 12 months following Y-90 ibritumomab tiuxetan (Zevalin®) antibody therapy
12. Patients with prior malignancy other than lymphoma, except for adequately-treated skin cancer, cervical cancer in situ, or other cancer for which the patient has been disease-free for 5 years

Date of first enrolment

21/04/2008

Date of final enrolment

20/04/2010

Locations

Countries of recruitment

United Kingdom

England

Wales

Study participating centre

Southampton General Hospital

Southampton University Hospitals NHS Trust

Somers Cancer Research Building, MP 824

Tremona Road

Southampton

United Kingdom

SO16 6YD

Study participating centre

North Wales Cancer Treatment Centre

Clinical Trials Unit

Glan Clwyd Hospital

Bodelwyddan

United Kingdom

LL18 5UJ

Study participating centre

St Bartholomew Hospital

West Smithfield

London

United Kingdom

EC1A 7BE

Study participating centre

Christie Hospital

Christie Hospital NHS Trust

Dept of Medical Oncology

Wilmslow Road

Withington

Manchester

United Kingdom

M20 4BX

Study participating centre

Poole Hospital

Poole Hospitals NHS Trust, Poole Hospital NHS Foundation Trust
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre

Weston Park Hospital

Sheffield Teaching Hospitals NHS Trust
Academic Unit of Clinical Oncology
Cancer Research Centre
Whitham Road
Sheffield
United Kingdom
S10 2SJ

Study participating centre

St Marys Hospital

Portsmouth Hospitals NHS Trust, Room 20, Exton 1
Portsmouth Oncology Centre
Portsmouth
United Kingdom
PO3 6AD

Study participating centre

Churchill Hospital

Oxford Radcliffe Hospitals NHS Trust
Research Institute
Oxford Cancer and Haematology Centre
Old Road
Headington
Oxford
United Kingdom
OX3 7LJ

Study participating centre

Mount Vernon Cancer Centre

East & North Hertfordshire NHS Trust (Mount Vernon)
Rickmansworth Road

Northwood
United Kingdom
HA6 2RN

Study participating centre

Royal Free Hospital

Royal Free Hospital NHS Trust
Dept of Academic Oncology
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre

Guys Hospital

Guys & St Thomas
Department of Haematology
4th Floor, Southwark Wing
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre

Addensbrookes Hospital

Cambridge Cancer Trials Centre
Oncology Clinical Trials (S4), Box 279
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre

St James's Hospital

Leeds Teaching Hospitals NHS Trust
Dept of Haematology
Level 3, Bexley Wing
Leeds
United Kingdom
LS9 7TF

Study participating centre**Velindre Cancer Centre**

Velindre Road
Whitchurch
Cardiff
United Kingdom
CF14 2TL

Study participating centre**St Georges Hospital**

St Georges Hospital, Research Nurses Office,
Lanesborough Wing Outpatients
Blackshaw Road
London
United Kingdom
SW17 0RE

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (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

Funder Name

Roche (Switzerland)

Alternative Name(s)

F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No
Plain English results			27/07/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes