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# 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

**Registration date**
10/07/2008

**Overall study status**
Completed

**Last Edited**
27/07/2022

**Condition category**
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**Study website**
http://www.ctu.soton.ac.uk/trial.aspx?trialid=16

## 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

**EudraCT/CTIS number**

### IRAS number

### ClinicalTrials.gov number
NCT00637832

### Secondary identifying numbers
2.0

# 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

### Secondary study design
Non randomised study

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

Not available in web format, please use the contact details provided in the Interventions field to request a patient information sheet.

## 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/m^2 (intravenous [IV]) + chemotherapy (R-Chemo)
Week 9: Rituximab IV 250 mg/m^2
Week 10: Rituximab followed by ibritumomab tiuxetan (Zevalin®). Dosage: Rituximab IV 250 mg /m^2; for Zevalin®: if platelet count >150 x 10^9L, Zevalin® at 14.8 MBq/kg, or if platelet count between >100 x 10^9L and <150 x 10^9L, 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 measure
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.

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

## Overall study start date
23/05/2008

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
80

### 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
England

United Kingdom

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)

### Sponsor details
Clinical Governance Directorate
Research & Development
Trust Management Offices, MP 18
Southampton General Hospital
Tremona Road
Southampton
England
United Kingdom
SO16 6YD

### Sponsor type
Hospital/treatment centre

### Website
http://www.suht.nhs.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, 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.

### Funding Body Type
Government organisation

### Funding Body Subtype
For-profit companies (industry)

### Location
Switzerland

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |