

# Phase II trial of single agent ofatumumab in relapsed/refractory mantle cell lymphoma

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|--|---|---|
| <b>Submission date</b><br>17/02/2011   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>17/02/2011 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>31/03/2022       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/-trial-looking-at-ofatumumab-for-mantle-cell-lymphoma>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2009-017675-16

### IRAS number

### ClinicalTrials.gov number

## Secondary identifying numbers

9760

# Study information

## Scientific Title

Multicentre non-randomised interventional treatment phase II trial of single agent ofatumumab in relapsed/refractory mantle cell lymphoma

## Acronym

Ofatumumab Study

## Study objectives

This is an open-label, phase II study of single agent ofatumumab in patients who have received one or more prior therapies for mantle cell lymphoma. This is a multicentre trial co-ordinated by the Plymouth Lymphoma Trials Unit, and sponsored by Plymouth Hospitals NHS Trust.

34 evaluable patients will receive single agent ofatumumab. This will be given as an intravenous infusion once a week for 5 weeks. The initial treatment of 300 mg will be commenced slowly starting at 12 ml/h, rising every 30 minutes to a maximum of 400 ml/h if no infusional reactions occur. Subject to patient tolerability, this dose and dose rate will be increased for subsequent infusions. A premedication of paracetamol, chlorphenamine (Piriton®) and prednisolone will be required prior to each infusion.

Response assessments will be performed 30 days after the final treatment and repeated after a further 3 months. Subsequent assessments will be performed as clinically required.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

South West 3 REC, 30/11/2010, ref: 10/H0106/66

## Study design

Multicentre non-randomised interventional treatment trial

## 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 below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Topic: National Cancer Research Network; Subtopic: Lymphoma; Disease: Lymphoma (non-Hodgkin's)

### **Interventions**

An ofatumumab infusion will be given once a week for 5 weeks. The initial infusion will be 300 mg, the four subsequent infusions will be 1000 mg each, subject to tolerability and toxicity.

This is a single arm study, with all patients being treated with Ofatumumab. After treatment, they will be followed for disease progression and survival.

Study entry: registration only

### **Intervention Type**

Drug

### **Phase**

Phase II

### **Drug/device/biological/vaccine name(s)**

Ofatumumab

### **Primary outcome measure**

To evaluate the rates of overall response to ofatumumab in terms of complete response (CR).

When 9 evaluable patients have received Ofatumumab an interim analysis will be performed. If two or more patients respond the trial will continue until a further 25 evaluable patients have received the research treatment.

### **Secondary outcome measures**

1. Disease progression
2. Liver toxicity
3. Other unacceptable toxicity
4. Withdrawal of patient consent

When 9 evaluable patients have received Ofatumumab an interim analysis will be performed. If two or more patients respond the trial will continue until a further 25 evaluable patients have received the research treatment.

### **Overall study start date**

17/01/2011

### **Completion date**

17/01/2013

## **Eligibility**

**Key inclusion criteria**

1. Male or female patients over the age of 18 years
2. A confirmed diagnosis of MCL including expression of cyclin D1 or evidence of t(11;14), by cytogenetics, fluorescent in situ hybridisation (FISH) or polymerase chain reaction (PCR)
3. Relapse/refractory MCL following the completion of a minimum of one previous course of cytotoxic chemotherapy treatment
4. All previous chemotherapy regimens are permissible (including those containing Rituximab)
5. Measurable disease
6. World Health Organization (WHO) score of 0 - 2
7. Absolute neutrophil count greater than or equal to 500 cells/ $\mu$ L not related to lymphoma
8. Platelets greater than or equal to 30,000 cells/ $\mu$ L not related to lymphoma
9. Toxic effects of previous therapy or surgery resolved to Grade 2 or better (with the exception of the haematological parameters discussed above)
10. Voluntary written informed consent before performance of any study-related procedure not part of normal medical care, with the understanding that consent may be withdrawn by the subject at any time without prejudice to future medical care

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 34; UK sample size: 34

**Total final enrolment**

12

**Key exclusion criteria**

1. Known serological positivity for hepatitis B virus (HBV), hepatitis C virus (HCV) or human immunodeficiency virus (HIV)
2. Anti-neoplastic therapy within 3 weeks before Day 1
3. Nitrosoureas within 6 weeks before Day 1
4. Radiation therapy within 3 weeks before Day 1
5. Rituximab, alemtuzumab (Campath®) or other unconjugated therapeutic antibody within three months before Day 1
6. Major surgery within 2 weeks before Day 1
7. Active systemic infection requiring treatment
8. Previous treatment or suspected hypersensitivity to Ofatumumab
9. Any concurrent active malignancy within the last 5 years patients who have a history of completely resected Non-melanoma skin cancer or in-situ carcinoma are eligible
10. Aspartate transaminase greater than 2.5 x upper limit of normal (ULN), or alanine transaminase greater than 2.5 x ULN, alkaline phosphatase greater than 2.5 x ULN unless due to disease involvement of the liver or bone

11. Total bilirubin greater than 1.5 x ULN unless due to liver involvement with MCL or known history of Gilbert's disease
12. Serum creatinine greater than 2.0 x ULN (unless normal creatinine clearance)
13. Female subject is pregnant or breast-feeding; confirmation of this will be required for female patients of child-bearing potential. For the purpose of this study, female of child-bearing potential is defined as women whose last menstrual period was less than one year prior to screening, unable or unwilling to use adequate contraception from study start to one year after the last dose of protocol therapy. Adequate contraception is defined as hormonal birth control, intrauterine device, double barrier method or total abstinence.
14. Male subjects unable or unwilling to use adequate contraception methods from study start to one year after the last dose of protocol therapy
15. Moderate or severe Chronic Obstructive Pulmonary Disease
16. Serious medical or psychiatric illness likely to interfere with participation in this clinical study
17. Treatment with another investigational agent for at least four weeks prior to enrolment into this study. Concurrent participation in non-treatment studies is allowed, if it does not interfere with participation in this study.
18. Subjects who have current active hepatic or biliary disease (with the exception of patients with Gilbert's syndrome, asymptomatic gallstones, liver metastases, or stable chronic liver disease. Patients with these conditions may be included subject to PI assessment).

**Date of first enrolment**

17/01/2011

**Date of final enrolment**

17/01/2013

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Lymphoma Trials Unit**

Plymouth

United Kingdom

PL6 8BX

## Sponsor information

**Organisation**

Plymouth Hospitals NHS Trust (UK)

**Sponsor details**

Derriford Hospital  
Derriford Road  
Plymouth  
England  
United Kingdom  
PL6 8DH

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.plymouthhospitals.nhs.uk/Pages/Home.aspx>

**ROR**

<https://ror.org/05x3jck08>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

GlaxoSmithKline

**Alternative Name(s)**

GlaxoSmithKline plc., GSK plc., GSK

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**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**

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                           | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>       | results | 01/05/2014   |            | Yes            | No              |
| <a href="#">Plain English results</a> |         |              | 31/03/2022 | No             | Yes             |
| <a href="#">HRA research summary</a>  |         |              | 28/06/2023 | No             | No              |