ISRCTN32524443 https://doi.org/10.1186/ISRCTN32524443

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

Submission date
17/02/2011

Recruitment status
No longer recruiting

Registration date
17/02/2011

Overall study status
Completed

Last Edited
31/03/2022

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/-trial-looking-at-ofatumumab-for-mantle-cell-lymphoma

Contact information

Type(s)
Scientific

Contact name
Mrs Sheila Bullard

Contact details
Lymphoma Trials Unit
N14, ITTC Building
Tamar Science Park
Derriford
Plymouth
United Kingdom
PL6 8BX
+44 (0)1752 437513
sheila.bullard@phnt.swest.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2009-017675-16

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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/µL not related to lymphoma
8. Platelets greater than or equal to 30,000 cells/µL 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Lymphoma Trials Unit
Plymouth
United Kingdom
PL6 8BX

Sponsor information

Organisation
Plymouth Hospitals NHS Trust (UK)

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

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