

# A phase II study of Gemcitabine and Bexarotene (GemBex) in the treatment of cutaneous T-cell lymphoma

<b>Submission date</b> 31/03/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/03/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-gemcitabine-and-bexarotene-for-people-with-t-cell-lymphoma-of-the-skin>

## Study website

<http://www.ctc.ucl.ac.uk>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2006-000591-33

### IRAS number

### ClinicalTrials.gov number

NCT00660231

## **Secondary identifying numbers**

1756

# **Study information**

## **Scientific Title**

A phase II, multicentre, non-randomised, open-label, single arm trial of the efficacy of Gemcitabine and Bexarotene in patients who have developed progressive cutaneous T-cell lymphoma (CTCL)

## **Acronym**

GemBex

## **Study objectives**

This is a phase II, multicentre, non-randomised, open-label, single arm trial of Gemcitabine and Bexarotene for the treatment of cutaneous T-cell lymphoma (CTCL) in patients who have developed progressive disease after receiving, or have been refractory to, standard skin-directed therapy and at least one prior systemic therapy. The study aims to to evaluate the efficacy of Gemcitabine and Bexarotene as a combination therapy in patients with CTCL in terms of the rate of objective disease response and its duration, and to determine whether the combination has sufficient biological activity in CTCL to warrant more extensive investigation. This is a "two stage" study where 35 patients will be treated initially and if the response criteria are met, further 49 to a total of 84 patients will be treated on the study.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Leeds (East) Research Ethics Committee, 10/05/2006, ref: 06/Q1206/65

## **Study design**

Non-randomised multicentre interventional and observational treatment validation of investigation/therapeutic process

## **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**

Prophylactic fenofibrate; patients start prophylactic Fenofibrate 160 - 200 mg daily 7 days before chemotherapy. Initial chemotherapy: 4 x 21 day cycles:

Gemcitabine 1000 mg/m<sup>2</sup> intravenous (iv) days 1 and 8

Bexarotene 300 mg/m<sup>2</sup> orally (po) daily\*

\* Bexarotene given at a reduced dose of 150 mg/m<sup>2</sup> for weeks 1 and 2 of cycle 1 and, if tolerated, increased to 300 mg/m<sup>2</sup> as per British Dermatology Society guidelines

In patients responding after 4 cycles of Gemcitabine + Bexarotene:

Bexarotene maintenance 300 mg/m<sup>2</sup> daily until disease progression or patient

Study Entry: Registration only

Details: As this is a single arm study, all patients registered will receive the same treatment.

### **Intervention Type**

Drug

### **Phase**

Phase II

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

Gemcitabine and Bexarotene (GemBex), Fenofibrate

### **Primary outcome measure**

To confirm the feasibility and efficacy of the combination of Gemcitabine and Bexarotene in patients, assessed during time from treatment start to progression

### **Secondary outcome measures**

Assessed during time from treatment start to progression:

1. To evaluate the rate of objective disease control
2. To evaluate the duration and durability

### **Overall study start date**

29/07/2008

### **Completion date**

31/07/2012

## **Eligibility**

### **Key inclusion criteria**

1. Males or non-pregnant females aged greater than 18 years
2. Histologically confirmed diagnosis of cutaneous T-cell lymphoma (CTCL), including mycosis

fungoides and Sézary syndrome

3. Stage Ib, IIa, IIb, III, IVa and IVb disease

4. Patients who have failed standard skin-directed therapy and have had at least 1 course of prior systemic therapy, such as interferon, chemotherapy, Denileukin diftitox (Ontak®) which they have either failed to respond to or have subsequently progressed

5. Anticipated life expectancy greater than six months

6. Written informed consent to participate in the study. vii. Bexarotene naive or previous response to single-agent bexarotene, but more than 3 months since last treatment with bexarotene

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Planned Sample Size: 84; UK Sample Size: 84

### **Key exclusion criteria**

1. Eastern Cooperative Oncology Group (ECOG) Performance Status greater than 1
2. Patients who have not received at least 1 course of prior systemic therapy for CTCL
3. CD30 + (Ki1+ve) anaplastic large cell lymphoma
4. Patients who have failed previous treatment with Bexarotene (Targretin®)
5. Patients who have previously experienced a severe adverse reaction to Bexarotene
6. Concomitant use of any anti-cancer therapy
7. Concomitant use of any investigational agent
8. Use of any investigational agent within 4 weeks of study entry
9. Clinically significant active infection
10. Known infection with human immunodeficiency virus (HIV), hepatitis B, or hepatitis C
11. Excessive alcohol consumption
12. Uncontrolled diabetes mellitus
13. Biliary tract disease
14. History of pancreatitis
15. Concomitant drug therapy with other medications that can elevate triglycerides or cause pancreatic toxicity e.g. Gemfibrozil
16. Inadequate bone marrow or other organ function, as evidenced by: Unsupported haemoglobin less than 9.0 g/dL (transfusions and/or erythropoietin are permitted); Absolute neutrophil count (ANC) =  $1.5 \times 10^9/L$ ; Platelet count less than  $100 \times 10^9/L$
17. Total bilirubin greater than 1.25 x upper limit of normal (ULN) for institution, aspartate transaminase/glutamic oxaloacetic transaminase (AST/SGOT) and alanine transaminase/glutamic pyruvic transaminase (ALT/SGPT) greater than 2.0 x ULN, serum creatinine greater than 2 x ULN for age and sex
18. Coexistent second malignancy or history of prior malignancy within previous 5 years (excluding basal or squamous cell carcinoma of the skin or cervical epithelial neoplasm [CIN1,

carcinoma in situ] that has been treated curatively)

19. Any significant medical or psychiatric condition that might prevent the patient from complying with all study procedures

20. Patients who are pregnant or breast-feeding (all women of child bearing potential must use the contraceptive pill or intrauterine contraceptive device (IUCD) during the treatment period and for at least 1 month thereafter). Male patients must use a barrier method of contraception during the treatment period and for at least 1 month thereafter.

21. Any treatment for lymphoma, including photopheresis, within the 4 weeks prior to entering the study. For patients receiving long-term corticosteroid therapy, the dose should ideally be stopped and if this is not feasible reduced to as low as possible. If steroids cannot be stopped, patients who have been on stable doses less than or equal to 20 mg for at least 3 months can be entered into the study. Local radiotherapy to isolated symptomatic tumour nodules requiring immediate treatment may be given until 2 weeks prior to entering the study.

22. Warfarin

**Date of first enrolment**

29/07/2008

**Date of final enrolment**

31/07/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Cancer Research UK & UCL Trials Centre**

London

United Kingdom

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## **Sponsor information**

**Organisation**

University College London (UCL) (UK)

**Sponsor details**

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United Kingdom

WC1E 6BT

**Sponsor type**

University/education

**Website**

<http://www.ucl.ac.uk/>

**ROR**

<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK (CRUK) (UK) (ref: C431/A6857)

**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

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs****Output type**

[Plain English results](#)

**Details****Date created****Date added****Peer reviewed?**

No

**Patient-facing?**

Yes

[Results article](#)

results

12/11/2013

Yes

No