ISRCTN18563749 https://doi.org/10.1186/ISRCTN18563749

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

Submission date 31/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2010	**Overall study status** Completed	
Last Edited 26/10/2018	**Condition category** Cancer	

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

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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^2 intravenous (iv) days 1 and 8
Bexarotene 300 mg/m^2 orally (po) daily*
* Bexarotene given at a reduced dose of 150 mg/m^2 for weeks 1 and 2 of cycle 1 and, if tolerated, increased to 300 mg/m^2 as per British Dermatology Society guidelines

In patients responding after 4 cycles of Gemcitabine + Bexarotene:
Bexarotene maintenance 300 mg/m^2 daily until disease progression or patient

Study Entry: Registration only
Details: As this is a single arm study, all patients registered will recieve 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 x 10^9/L; Platelet count less than 100 x 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
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Sponsor information

Organisation
University College London (UCL) (UK)

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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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results				No	Yes

Results article	results	12/11/2013	Yes	No