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A study of GCS-100 in combination with chemo-immunotherapy in patients with diffuse large B-cell lymphoma which have relapsed or are refractory to treatment

Submission date 15/10/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/10/2008	**Overall study status** Stopped	
Last Edited 16/10/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PR-CS011

Study information

Scientific Title
A phase II study of GCS-100 in combination with chemo-immunotherapy in relapsed or refractory diffuse large B-cell lymphoma

Study objectives
The primary objective of this study is to assess the efficacy of GCS-100 with rituximab, ifosfomide, mesna, carboplatin and etoposide (R-ICE) chemotherapy in subjects with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The secondary objective is to determine the safety of GCS-100 in conjunction with cytotoxic chemotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the London Research Ethics Committee (REC) of Northwick Park Hospital on the 6th October 2008 (ref: 08/H0718/57)

Study design
Interventional, single-arm, single-centre trial

Primary study design
Interventional

Secondary study design
Single-centre

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
Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Interventions
This is a single-arm trial of GCS-100 with R-ICE chemotherapy administered in 21-day cycles (a maximum of four chemotherapy cycles per participant). Each 21-day treatment cycle consists of the following:

Days 1 - 5: GCS-100 160 mg/m^2/day intravenously (IV) over 1 hour.

Dosing with GCS-100 will be followed at least 1 hour later by:
Day 1: rituximab 375 mg/m^2 IV
Days 2: carboplatin dose area under the curve (AUC) = 5 mg/mL x min (maximum 800 mg) IV
Days 2 - 4: ifosfamide 1667 mg/m^2 IV
Days 2 - 4: mesna 1667 mg/m^2 IV or oral
Days 2 - 4: etoposide 100 mg/m^2 IV

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
GCS-100, rituximab, ifosfomide, mesna, carboplatin, etoposide

Primary outcome measure
1. Response: overall response rate, defined as the sum of the number of CR rate and PR rate. CR and PR will be defined according to the International Harmonisation Project for Lymphoma criteria.
2. Imaging: CT scans will be obtained at baseline and every two cycles to assess for response. They will be evaluated according to the International Harmonisation Project for Lymphoma.

Total duration of follow-up for the primary and secondary outcome measures: 16 weeks.

Secondary outcome measures
To determine the safety of GCS-100 in conjunction with cytotoxic chemotherapy by collecting adverse event data and monitoring blood parameters, etc. Total duration of follow-up for the primary and secondary outcome measures: 16 weeks.

Overall study start date
01/12/2008

Completion date
01/12/2009

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
1. Subject is capable of understanding the purpose and risks of the study and is able to provide written informed consent
2. Subject is male or female, aged at least 18 years
3. Subject has histologically confirmed DLBCL, bidimensionally measurable by computerised tomography (CT) scan, with at least one lesion greater than or equal to 1.5 cm in the greatest diameter. CT scan results must be available prior to dosing to establish eligibility.
4. Subject has relapsed or relapsed/refractory disease following at least two cycles of R-ICE chemotherapy as salvage chemotherapy, without partial response (PR) or complete response

(CR)
5. Subject has greater than or equal to 4 weeks elapsed between last chemotherapy or immunotherapy exposure
6. Subject has Eastern Collaborative Oncology Group (ECOG) performance status of 0 or 1

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
14 - 28

Key exclusion criteria
1. Subject has received high-dose chemotherapy with haematopoietic stem cell support or allogeneic stem cell transplantation (SCT)
3. Subject has rapidly progressive lymphoma or lymphoma threatening organ function
4. Subjects with primary or secondary central nervous system lymphoma
5. Subjects who have had treatment with an experimental (unlicensed) drug within 3 weeks prior to treatment with GCS-100
6. Subject has not recovered from all toxic effects of previous chemotherapy, radiation therapy, biologic therapy, and/or experimental therapy
7. Subject has a known history of human immunodeficiency virus-related lymphoma, active hepatitis C, active hepatitis B, or prior history of infection with hepatitis B (HBcAb positive)
8. Subject has a clinically relevant active infection and/or a serious co-morbid medical condition such as recent myocardial infarction (within the last 6 months and no electrocardiographic evidence of acute ischaemia or new conduction system abnormalities), unstable angina, difficult-to-control congestive heart failure, uncontrolled hypertension, difficult-to-control cardiac arrhythmias, chronic obstructive or chronic restrictive pulmonary disease, and/or cirrhosis.
9. Subject had major surgery within 4 weeks prior to study day 1

Date of first enrolment
01/12/2008

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Barts and the London NHS Trust
London
United Kingdom
EC1A 7BE

Sponsor information

Organisation
Prospect Therapeutics, Inc. (USA)

Sponsor details
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MA 01801

Sponsor type
Industry

Website
http://www.prospectthera.com

Funder(s)

Funder type
Industry

Funder Name
Prospect Therapeutics, Inc. (USA)

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?
HRA research summary			28/06/2023	No	No