

Single-arm phase II to evaluate the safety and efficacy of Campath in combination with high-dose methylprednisolone in CLL patients with deletion of the p53 tumour suppressor gene.

Submission date 19/08/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/10/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-into-alemtuzumab-and-methylprednisolone-for-people-with-chronic-lymphocytic-leukaemia-with-a-p53-gene-defect>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2005-003729-18

IRAS number

ClinicalTrials.gov number

NCT00292760

Secondary identifying numbers

2514

Study information

Scientific Title

Single-arm phase II to evaluate the safety and efficacy of Campath in combination with high-dose methylprednisolone in CLL patients with deletion of the p53 tumour suppressor gene.

Acronym

UKCLL206 (CAM-PRED)

Study objectives

A single-arm phase II study of alemtuzumab and high-dose methylprednisolone (Cam-Pred) in chronic lymphocytic leukaemia (CLL) patients with P53 deletion. The objectives are to assess the safety and efficacy of the combination of alemtuzumab and high-dose methylprednisolone in CLL patients with P53 deletion. this is a phase II open label study of untreated or previously treated patients with CLL or small lymphocytic lymphoma (SLL), whose CLL clone has a P53 gene deletion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC, 18/12/2005, ref: 05/MRE04/64

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: Haematological Oncology; Disease: Leukaemia (chronic)

Interventions

1. Beta2M
2. Buccal smear for comparison with tumour-cell DNA and 'tissue banking
3. Chest x-ray
4. Cytomegalovirus (CMV) serology and quantitative polymerase chain reaction (PCR) (or antigen testing according to local practice)
5. Coombs test
6. Computed tomography (CT) scan of neck, chest, abdomen and pelvis
7. EDTA: a 'first-pull' bone marrow aspirate sample should be collected in EDTA
8. Full blood count (FBC)
9. Lactate dehydrogenase (LDH)
10. P53 analysis, 50 ml blood for P53 analysis and 'tissue banking', plus a 5ml EDTA sample for diagnosis and morphological assesment
11. Pregnancy testing (if female and of child bearing potential)
12. Reticulocyte count
12. Serum immunoglobulins and electroporhesis
13. Bone marrow trephine biopsy
14. Urea and electrolytes (U&Es), liver function tests (LFTs), blood glucose and uric acid

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Alemtuzumab, methylprednisolone

Primary outcome measure

Response rate (partial response [PR] and complete response [CR]) and MRD negativity rate achieved by the combinaton of alemtuzumab and high dose methylprednisolone

Secondary outcome measures

Safety of Cam-Pred in P53 deleted CLL

Overall study start date

19/06/2006

Completion date

13/02/2008

Eligibility

Key inclusion criteria

1. At least 18 years old, either sex
2. Written informed consent

3. Confirmed diagnosis of CLL or SLL (small mature lymphocytes in blood, bone marrow or lymph node expressing CD19, CD5, CD23, weak CD79b, and weak clonally restricted immunoglobulin light chain)
4. p53 deletion by FISH in at least 20% of leukaemia cells
5. Treatment is indicated (Binet stage B or C, or stage A with a lymphocyte doubling time of less than 6 months, or disease-related symptoms or complications irrespective of clinical stage)
6. World Health Organization (WHO) performance status 0, 1 or 2
7. Both untreated and previously treated patients are eligible for study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 40; UK sample size: 40

Key exclusion criteria

1. Active infection
2. Known human immunodeficiency virus (HIV) infection
3. Past history of anaphylaxis following exposure to rat or mouse CDR-grafted humanised monoclonal antibodies
4. Less than 3 weeks since prior chemotherapy
5. Use of prior investigational agents within 6 weeks
6. Pregnancy or lactation
7. Uncontrolled diabetes mellitus
8. Uncontrolled hypertension
9. Active peptic ulcer disease
10. Other severe concurrent diseases or mental disorders
11. Serum urea or creatinine more than twice the upper limit of normal (unless due to ureteric obstruction or renal infiltration by CLL/SLL)
12. Serum bilirubin more than twice the upper limit of normal (unless due to haemolysis or liver infiltration with CLL/SLL)
13. Persisting severe cytopenias due to previous therapy rather than disease (neutrophils less than $0.5 \times 10^9/l$ or platelets less than $50 \times 10^9/l$)

Date of first enrolment

19/06/2006

Date of final enrolment

13/02/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Royal Liverpool University Hospital

Liverpool

United Kingdom

L7 8XP

Sponsor information**Organisation**

University of Liverpool (UK)

Sponsor details

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Liverpool

England

United Kingdom

L69 3BX

Sponsor type

University/education

Website

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

ROR

<https://ror.org/04xs57h96>

Funder(s)**Funder type**

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C18029/A5921)

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	10/05/2012		Yes	No