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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

Registration date
19/08/2010

Overall study status
Completed

Last Edited
19/10/2018

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Ms Stacey Gerard

Contact details
Bone Marrow Transplant Unit
10th Floor, Prescot Street
Liverpool
United Kingdom
L7 8XP
-
Stacey.Gerard@rlbuht.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00292760

Clinical Trials Information System (CTIS)
2005-003729-18

Protocol serial number
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

Primary study design
Interventional

Study design
Multicentre non-randomised interventional treatment trial

Study type(s)
Treatment

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

Key secondary outcome(s)
Safety of Cam-Pred in P53 deleted CLL

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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 x 10^9/l or platelets less than 50 x 10^9/l)

Date of first enrolment
19/06/2006

Date of final enrolment
13/02/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Liverpool University Hospital
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
University of Liverpool (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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/05/2012		Yes	No
Plain English results				No	Yes