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Eradication of minimal residual disease (MRD) in chronic lymphocytic leukaemia (CLL) with alemtuzumab: a Phase II study

Submission date
06/01/2006

Recruitment status
No longer recruiting

Registration date
20/01/2006

Overall study status
Completed

Last Edited
29/03/2022

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-alemtuzumab-after-chemotherapy-for-chronic-lymphocytic-leukaemia-cll207-mrd-eradication-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2006-000053-22

IRAS number

ClinicalTrials.gov number
NCT00458523

Secondary identifying numbers
UKCLL07

Study information

Scientific Title
Eradication of minimal residual disease (MRD) in chronic lymphocytic leukaemia (CLL) with alemtuzumab: a Phase II study

Acronym
UKCLL07

Study objectives
1. Is alemtuzumab effective and safe at treating patients with CLL whose disease is present at a low level following conventional treatments?
2. There will also be an investigation where MRD negative patients are monitored and retreated when necessary.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre open-label single-arm study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic lymphocytic leukaemia (CLL)

Interventions

Patients who have previously achieved a minimal residual disease (MRD) negative remission and have relapsed at a molecular level, or who have a low level of MRD following conventional therapy will receive treatment for a minimum of 6 weeks (3 times per week) and a maximum of 12 weeks. Patients who have achieved an MRD negative state by conventional therapy may register for the study but will not be treated with alemtuzumab until CLL becomes detectable again.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Alemtuzumab

Primary outcome measure
1. Rate of achieving MRD negativity in patients with low levels of MRD following conventional therapy or who relapse at an MRD level after a previous MRD negative remission
2. Safety of alemtuzumab in the MRD positive setting

Secondary outcome measures
1. Clinical response to alemtuzumab therapy by National Cancer Institute (NCI) Criteria
2. Overall survival
3. Pharmacokinetic profile of alemtuzumab in the MRD setting
4. Safety and efficacy of repeated dosing as required to achieve sustained MRD negativity

Outcome of additional Monitoring Investigation (patients who are MRD negative at registration):
1. Time to MRD relapse
2. Effect of alemtuzumab used in a consolidation/maintenance approach on the expression of CD52 on CLL cells

Overall study start date
01/03/2006

Completion date
29/02/2008

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Written informed consent
3. Previous confirmation of B-cell CLL with a characteristic immunophenotype on peripheral blood flow cytometry
4. Creatinine and bilirubin <2 x upper limit of normal unless secondary to direct infiltration of the liver by CLL or haemolysis
5. Must have achieved a complete remission or good partial remission after therapy for CLL
6. At least six months since completing last therapy for CLL
7. Have detectable MRD, as shown by peripheral blood or bone marrow involvement or have

attained an MRD negative remission. The latter group is eligible for registration and three-monthly monitoring for MRD relapse

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
54

Total final enrolment
47

Key exclusion criteria
1. Lymph nodes of 2 cm or greater in maximum diameter
2. Known Human Immunodeficiency Virus (HIV) positive
3. Active infection
4. Past history of anaphylaxis following exposure to rat or mouse derived Commonly Deleted Region (CDR)-grafted humanised monoclonal antibodies
5. Use of prior investigational agents within six weeks
6. Pregnancy or lactation
7. Central Nervous System (CNS) involvement with CLL
8. Mantle cell lymphoma
9. Other severe, concurrent diseases or mental disorders
10. Active secondary malignancy
11. Persisting severe pancytopenia due to previous therapy rather than disease (neutrophils <0.5 x 109/l or platelets <50 x 109/l)
12. Patients previously treated with allogeneic Stem Cell Transplantation (SCT)
13. Patients who previously failed alemtuzumab therapy

Date of first enrolment
01/03/2006

Date of final enrolment
29/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds General Infirmary
Leeds
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Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

Sponsor details
Department of Research and Development
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Industry

Funder Name
Schering Health Care Ltd (funding reference no. UKCLL07)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2017		Yes	No
Plain English results		10/07/2017	29/03/2022	No	Yes