

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/03/2022	Condition category Cancer	<input type="checkbox"/> 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

Contact name

Dr Peter Hillmen

Contact details

Department of Haematology
Brotherton Wing
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX
+44 (0)113 392 3766
peter.hillmen@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)

2006-000053-22

ClinicalTrials.gov (NCT)

NCT00458523

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 $<2 \times$ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 $<0.5 \times 10^9/l$ or platelets $<50 \times 10^9/l$)
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

United Kingdom

England

Study participating centre

Leeds General Infirmary

Leeds

United Kingdom

LS1 3EX

Sponsor information

Organisation

Leeds Teaching Hospitals NHS Trust (UK)

ROR

<https://ror.org/00v4dac24>

Funder(s)

Funder type

Industry

Funder Name

Schering Health Care Ltd (funding reference no. UKCLL07)

Results and Publications

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