

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

<b>Submission date</b> 06/01/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/03/2022	<b>Condition category</b> 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

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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  $<2 \times$  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

**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  $<0.5 \times 10^9/l$  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**

England

United Kingdom

**Study participating centre**  
**Leeds General Infirmary**  
Leeds  
United Kingdom  
LS1 3EX

## **Sponsor information**

**Organisation**  
Leeds Teaching Hospitals NHS Trust (UK)

**Sponsor details**  
Department of Research and Development  
Leeds Teaching Hospitals NHS Trust  
6th Floor Wellcome Wing  
Leeds General Infirmary  
Great George Street  
Leeds  
England  
United Kingdom  
LS1 3EX

**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?
<a href="#">Results article</a>	results	01/02/2017		Yes	No
<a href="#">Plain English results</a>		10/07/2017	29/03/2022	No	Yes