

Chronic lymphocytic leukaemia (CLL) unrelated and related allogeneic transplantation in very high risk disease for leukaemia eradication trial

Submission date 10/08/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/06/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-001669-27

Protocol serial number
CLLX2

Study information

Scientific Title

A phase III study on the value of allogeneic stem cell transplantation in poor-risk chronic lymphocytic leukaemia

Acronym

CLLX2

Study objectives

Allogeneic stem cell transplantation (allo-SCT) with reduced-intensity conditioning (RIC) can increase event-free survival (EFS) 2 years after randomisation from 40% to 70% (high-risk CLL) and from 10% to 40% (very high-risk CLL), respectively, in comparison with conventional treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised phase III active controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

High-risk and very high-risk chronic lymphocytic leukaemia (CLL)

Interventions

Stratum 1: Patients achieving complete remission (CR)/partial remission (PR) after three cycles of salvage and having an HLA-identical donor at 3 months landmark (LM) are randomised 1:1 to RIC allo-SCT (experimental intervention) or to three additional cycles of salvage (control intervention).

Stratum 2: All eligible patients will undergo biological randomisation at the 3-month LM: Patients with an HLA-compatible donor available 3 month after registration will proceed to RIC allo-SCT (donor arm-experimental intervention). Patient without donor will receive non-transplant consolidation treatment or observation (no donor arm - control intervention).

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

EFS 2 years after randomisation, in comparison with conventional treatment.

Key secondary outcome(s)

Measured at patient recruitment and then at 12 and 24 months after randomisation:

1. 5-year overall survival (OS) from randomisation; 5-year OS from registration (Stratum 2 only)
2. Clinical response
3. Safety from any cause
4. Non-relapse mortality
5. Morbidity
6. Chronic graft-versus-host disease
7. Quality of life, measured using the EORTC questionnaire

Completion date

01/03/2015

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years, either sex
2. World Health Organization performance status (WHO PS) grade 0 - 1
3. Active and measurable high risk CLL (Stratum 1) or very high risk CLL (Stratum 2)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Patients unable to withstand RIC allo-SCT
2. Participation in another clinical trial

Date of first enrolment

01/01/2010

Date of final enrolment

01/03/2015

Locations

Countries of recruitment

Austria

Canada

Germany

Switzerland

Study participating centre
Department of Internal Medicine V
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

ROR
<https://ror.org/013czdx64>

Funder(s)

Funder type
Research organisation

Funder Name
German Cooperative Transplant Study Group (GCTSG) (Germany)

Funder Name
German Chronic Lymphocytic Leukaemia Study Group (GCLLSG) (Germany)

Results and Publications

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?
Basic results			25/06/2020	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes