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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/11/2009	**Overall study status** Completed	
Last Edited 25/06/2020	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.dcllsg.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2008-001669-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at: http://www.dcllsg.de

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

Secondary outcome measures
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

Overall study start date
01/01/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

206

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)

Sponsor details
c/o Prof Dr Michael Hallek
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Sponsor type
University/education

Website

http://www.med.uni-heidelberg.de/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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