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The value of autografting younger patients with high risk chronic lymphocytic leukaemia (CLL). A randomised phase III intergroup trial

Submission date 02/05/2001	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/05/2001	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-the-timing-of-transplants-using-a-patients-own-stem-cells-for-chronic-lymphocytic-leukaemia

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G0001160

Study information

Scientific Title
The value of autografting younger patients with high risk chronic lymphocytic leukaemia (CLL). A randomised phase III intergroup trial

Acronym
MRC CLL5

Study objectives
This is a prospective randomised phase III trial designed to determine the outcome of autologous SCT compared to no further treatment at present in patients with high risk CLL who have reached a complete remission (CR), a very good partial remission (VGPR) or a nodular partial remission (NPR) after first or second line therapy.

The MRC CLL5 protocol is avaialble on http://www.ebmt.org/5WorkingParties/CLWP/CLL5/MRC_CLL5_protocol.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Leukaemia

Interventions
In this trial, younger patients with chronic lymphocytic leukaemia who are thought to be medically fit for autologous transplantation will be treated to maximal response with standard chemotherapy. Patients will then be randomised to undergo stem cell mobilisation followed by a cyclophosphamide/total body irradiation conditioned autograft. Purging of the stem cell product is optional.

Those patients not randomised to have an autograft will have the option of stem cell storage to be used at a later date.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)

Primary endpoints:
1. Progression free survival from randomisation
2. Overall survival from randomisation

Key secondary outcome(s)
Secondary endpoints:
1. Time to disease requiring therapy from time of remission
2. Quality of life
3. Feasibility of first line versus late stem cell transplant
4. Feasibility of peripheral blood mobilisation

Completion date
16/01/2008

Eligibility

Key inclusion criteria
1. B CLL CD5+/CD23+
2. There is no upper age limit but patients must be judged physically able to withstand high-dose chemotherapy and the suitability of this treatment may be discussed with the Transplant Centre
3. Binet stage (at initiation of first line treatment) B, C, or progressive A
4. Complete Remission (CR) or Very Good Partial Remission (VGPR) or Nodular Partial Remission (NPR) assessed by bone marrow biopsy after first or second line treatment
5. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Total final enrolment
223

Key exclusion criteria
1. Age less than 18
2. WHO Performance status less than 2
3. Any T-cell leukaemia, NHL, Richter syndrome, mantle cell lymphoma, PLL
4. HIV seropositivity.
5. Inadequate renal or liver function, i.e. creatinine and bilirubin less than 1.5 times the upper limit of normal
6. Severe heart failure, requiring diuretics or ejection fraction of less than 50%
7. Severe concomitant neurological or psychiatric disease
8. Pregnancy/lactation

9. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; these conditions should be discussed with the patient before registration in the trial.
10. Patients will be excluded if an allograft is planned

Date of first enrolment
17/01/2002

Date of final enrolment
16/01/2008

Locations

Countries of recruitment
United Kingdom

England

France

Germany

Switzerland

Study participating centre
Department of Haematology
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	03/02/2011		Yes	No
Plain English results			26/10/2022	No	Yes