

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 02/05/2001 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 02/05/2001 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 26/10/2022 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 available 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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

Primary endpoints:

1. Progression free survival from randomisation
2. Overall survival from randomisation

Secondary outcome measures

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

Overall study start date

17/01/2002

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

Age group

Adult

Sex

Not Specified

Target number of participants

Total 270 - UK anticipated to contribute approximately 125 patients

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**

England

France

Germany

Switzerland

United Kingdom

Study participating centre

Department of Haematology

Birmingham

United Kingdom

B9 5SS

Sponsor information

Organisation

Heart of England NHS Foundation Trust (UK)

Sponsor details

Birmingham Heartlands Hospital

Bordesley Green East

Birmingham

England

United Kingdom

B9 5SS

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not@provided.com

Sponsor type

Hospital/treatment centre

Website

<http://www.heartofengland.nhs.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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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? |
|---------------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 03/02/2011 | | Yes | No |
| Plain English results | | | 26/10/2022 | No | Yes |