

A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia

Submission date 23/04/2010	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 23/04/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/12/2020	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-treatment-adults-with-acute-lymphoblastic-leukaemia-UKALL14>

Contact information

Type(s)

Scientific

Contact name

Mr Kalam Hussain

Contact details

CRUK and UCL Cancer Trials Centre
90 Tottenham Court Road
London
United Kingdom
W1T 4TJ
+44 (0)207 679 9169
ukall14@ctc.ucl.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)

NCT01085617

Clinical Trials Information System (CTIS)

2009-012717-22

Protocol serial number

7471

Study information

Scientific Title

A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia

Acronym

UKALL 14

Study objectives

- 1.1. 1B (precursor-B lineage): to determine if the addition of rituximab to standard induction chemotherapy results in improved event-free survival (EFS) in patients with precursor B-cell lineage acute lymphoblastic leukaemia (ALL)
- 1.2. 1T (T lineage): to determine if the addition of nelarabine following standard induction therapy (arms T1 and T2) improves outcome for patients with T cell ALL
2. To determine the tolerability of Pegylated asparaginase in induction (for all patients) and to compare anti-asparaginase antibody levels between patients in the 2 randomisation groups from aim 1B
3. To determine whether risk-adapted introduction of unrelated donor HSCT (myeloablative conditioning in patients aged up to and including 40 years at time of study entry and non-myeloablative conditioning in patients aged greater than 40 years, i.e., having reached their 41st birthday at time of study entry) result in greater EFS for patients at highest risk of relapse
4. To compare 2 schedules of administration (standard P1 versus 'collapsed' P2) of keratinocyte growth factor (palifermin) for efficacy in preventing the severe mucosal toxicity of etoposide /TBI HSCT conditioning regimen

Ethics approval required

Old ethics approval format

Ethics approval(s)

West London REC 2, 13/01/2010, ref: 09/H0711/90

Primary study design

Interventional

Study design

Randomised interventional treatment trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute lymphoblastic leukaemia

Interventions

Rituximab: To determine if the addition of monoclonal antibody to standard induction chemotherapy results in improved EFS in patients with precursor B-cell lineage ALL
Nelarabine: To determine if the addition of nelarabine following standard induction therapy (arms T 1 and T2) improves outcome for patients with T cell ALL
Oncaspar: To determine the tolerability of pegylated asparaginase in induction (for all patients) and to compare anti-asparaginase

1. Rituximab: 375 mg/m² given by IV on days 3, 10, 17 and 24 of Phase 1 induction therapy
2. Oncaspar: 1000 IU/m² given by IV on days 4 and 18 of Phase 1 induction therapy
3. Nelarabine: 1.5 g/m² given by IV on days 1, 3 and 5 immediately following Phase 2 induction therapy
4. Palifermin: 60 ug/kg given either on days -10, -9, -8, 0, 2 and 4 or -9, 0, 2 and 4 of myeloablative conditioning regimen

Total duration of treatment is approximately 2 years 6 months for all patients who complete treatment. Patients are followed up until death.

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

1. Event free survival (applies to all interventions), measured from date of randomisation until the date of relapse
2. Toxicity related to pegylated asparaginase, measured after Phase 1 induction therapy

Key secondary outcome(s)

1. Anti-asparaginase antibodies (induction randomisation only), measured at the end of Phase 1 induction therapy
2. Overall survival, measured from date of randomisation until date of death
3. Complete remission rate: % of patients in complete remission at the end of Phase 2 induction therapy

Completion date

31/07/2022

Eligibility

Key inclusion criteria

1. Subjects must be aged greater than or equal to 25 and less than or equal to 65 years old with acute lymphoblastic leukaemia, either sex
2. Newly diagnosed, previously untreated ALL (a steroid pre-phase of 5 - 7 days is acceptable and can be started prior to registration)
3. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Known HIV infection
2. Pregnant or lactating women
3. Blast transformation of CML
4. Mature B-cell leukemia, i.e. Burkitt's disease t(8,14)(q24 ;q32) and all disorders amplification of c-myc, e.g. t(2;8)(p12q24), t(8;22)(q24;q11)

Date of first enrolment

30/12/2010

Date of final enrolment

31/12/2020

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Haematology Trials Group

London

United Kingdom

W1T 4TJ

Sponsor information**Organisation**

University College London (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)**Funder type**

Charity

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

In line with the CR UK and UCL CTC policy the unit is committed to supporting safe and appropriate sharing and requests for access to the participant level data should be made by contacting the relevant Trials Group Lead, Director or Deputy Director.
All requests will be assessed by the relevant Chief Investigator/Trial Management Group and, if necessary, Trial Steering Committee and/or CTC Senior Management Group. Please see the UCL CTC website for further details: <http://www.ctc.ucl.ac.uk/DataSampleSharing.aspx>

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/07/2018	25/06/2019	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes