ISRCTN66541317 https://doi.org/10.1186/ISRCTN66541317

A randomised trial for adults with newly diagnosed acute lymphoblastic leukaemia

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-treatment-adults-with-acute-lymphoblastic-leukaemia-UKALL14

Study website
https://www.ctc.ucl.ac.uk/TrialDetails.aspx?Trial=80&term=ukall14

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-012717-22

IRAS number

ClinicalTrials.gov number

NCT01085617

Secondary identifying numbers
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

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2008

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

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 811; UK sample size: 811

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
England

United Kingdom

Study participating centre
Haematology Trials Group
London
United Kingdom
W1T 4TJ

Sponsor information

Organisation
University College London (UK)

Sponsor details
Gower Street
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) grant (ref: C27995/A9609)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/07/2023

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