

An International Collaborative Trial for Relapsed and Refractory Acute Lymphoblastic Leukaemia

Submission date 01/10/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/10/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/03/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-treatment-for-children-and-young-people-with-acute-lymphoblastic-leukaemia>

Contact information

Type(s)

Scientific

Contact name

Prof Vaskar Saha

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2004-000052-16

ClinicalTrials.gov (NCT)

NCT00967057

Protocol serial number

N/A

Study information

Scientific Title

An International Collaborative Trial for Relapsed and Refractory Acute Lymphoblastic Leukaemia

Acronym

ALLR3

Study objectives

To examine the biology of relapsed Acute Lymphoblastic Leukaemia (ALL) and improve its outcome using a combination of chemotherapy and nationally standardised approach to Haematopoietic Stem Cell Transplantation (HSCT).

Please note that as of 13/05/10 this record has been extensively updated. Ireland, Australia, New Zealand and the Netherlands have been added to the countries of recruitment. The end date of this trial has also been extended from 01/01/2010 to 31/12/2011. All other updates can be found in the relevant field with the above update date.

Please note that the primary contact has moved insitution, therefore as of 13/05/10 the contact and sponsor details have been updated. The previous sponsor and contact details are as follows.
Previous sponsor:

Barts and the London NHS Trust (UK)
Research and Development Department
3rd Floor Rutland House
42-46 New Road
Whitechapel
London
E1 2AX
United Kingdom
<http://www.bartsandthelondon.org.uk>

Previous contact address:

Dept of Paediatric Oncology and Haematology
1st Floor Eva Luckes House
Royal London Hospital
London
E1 1BB
United Kingdom

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Multicentre Research Ethics Committee for Wales (ref: 02/9 /21)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Relapsed and Refractory Acute Lymphoblastic Leukaemia (ALL)

Interventions

No additional procedures are required in the trial. The trial drugs have already been used in previous paediatric oncology trials for many years.

Randomisation closed December 2007

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Added 13/05/2010:

1. Evaluate Progression Free Survival (PFS) by risk group
2. Evaluate whether a minimal residual disease level (MRD) level of 10^{-4} is a suitable criteria at the end of induction on which to decide whether chemotherapy or stem cell transplantation (SCT) will be most beneficial to patients in the intermediate risk group.

Key secondary outcome(s)

Added 13/05/2010:

1. MRD as a surrogate marker for PFS
2. Randomised comparison between Mitoxantrone and Idarubicin

Completion date

31/12/2011

Eligibility**Key inclusion criteria**

1. All children aged 1 - 18 years who have been previously diagnosed to have acute lymphoblastic leukaemia and have either relapsed after treatment or have primary refractory disease
2. For children who have relapsed, only those in whom this is the first relapse are eligible
3. Provide signed, written informed consent from parent and/or guardian
4. Protocol to have received national local ethical committee approval

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 years

Upper age limit

18 years

Sex

All

Key exclusion criteria

1. Children less than 1 year old and young adults of 18 years of age and older
2. Children in whom this is not the first relapse of their disease
3. Children with first relapse who have already received chemotherapy or radiotherapy prior to starting R3
4. Children with mature B cell ALL

Date of first enrolment

06/01/2003

Date of final enrolment

31/12/2011

Locations**Countries of recruitment**

United Kingdom

England

Australia

Ireland

Netherlands

New Zealand

Study participating centre

University of Manchester

Manchester

United Kingdom

M20 4BX

Sponsor information

Organisation

Central Manchester University Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (UK) (ref: ONPG1A1R) - Funding for trial manager

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/12/2010		Yes	No
Results article	results	03/10/2014		Yes	No
Results article	results	01/04/2019		Yes	No

