An International Collaborative Trial for Relapsed and Refractory Acute Lymphoblastic Leukaemia

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/10/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
01/10/2003	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/03/2019	Cancer			

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

EudraCT/CTIS number

2004-000052-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 recuitment. 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

Added 13/05/2010:

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

Overall study start date

06/01/2003

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

Age group

Child

Lower age limit

1 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

480

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

Australia

England

Ireland

Netherlands

New Zealand

United Kingdom

Study participating centre University of Manchester Manchester United Kingdom M20 4BX

Sponsor information

Organisation

Central Manchester University Hospitals NHS Foundation Trust (UK)

Sponsor details

Trust HQ Corbett House Manchester Royal Infirmary Oxford Road Manchester England United Kingdom M13 9WL

Sponsor type

Hospital/treatment centre

Website

http://www.cmft.nhs.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, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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

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	11/12/2010		Yes	No
Results article	results	03/10/2014		Yes	No
Results article	results	01/04/2019		Yes	No