

CLOfarabine (Clolar®) Used with DaunoXome® in acute myeloid leukaemia

Submission date 21/10/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/02/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/03/2017	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/trial-clofarabine-and-liposomal-daunorubicin-for-children-and-teenagers-with-acute-myeloid-leukaemia-cloud>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

RG_08-016

Study information

Scientific Title

Phase I escalation study of clofarabine (Clolar®) and liposomal daunorubicin (DaunoXome®) in childhood and adolescent acute myeloid leukaemia

Acronym

CLOUD

Study objectives

To establish the maximum tolerated dose of clofarabine (Clolar®) when used in combination with DaunoXome®.

On 01/03/2011 the anticipated end date was changed from 01/06/2010 to 30/06/2011.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Amended 11/02/2010: West Midlands Research Ethics Committee, 10/02/2009, ref: 08/H1208/36

Primary study design

Interventional

Study design

Multicentre prospective non blinded open label phase I dose escalation study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute myeloid leukaemia

Interventions

The calculation of dosage is based on the patients body surface area. The dose of DaunoXome® is fixed for all cohorts at 60 mg/m². DaunoXome® is given intravenously over 2 hours and start 4 hours after the start of Clofarabine (Clolar®) on days 1, 3 and 5. The starting dose of Clofarabine (Clolar®) will be 60% of the recommended single agent dose for the paediatric population. Clofarabine (Clolar®) is given intravenously over 2 hours on days 1, 2, 3, 4 and 5. Dose escalations in subsequent cohorts will approximate 33% increments.

The following dose levels will be studied:

Level -1: 20 mg/m²/day x 5 days

Level 0: 30 mg/m²/day/ x 5 days

Level 1: 40 mg/m²/day x 5 days

Dose escalation will be capped at 40 mg/m²/day. Patients will receive a single cycle of treatment and will be followed up until day 42.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

Clofarabine (Clolar®), daunorubicin (DaunoXome®)

Primary outcome(s)

To establish the maximum tolerated dose of clofarabine (Clolar®) when used in combination with DaunoXome®. The maximum tolerated dose will be defined by the number of dose-limiting toxicities during cycle 1 of therapy.

Key secondary outcome(s)

1. To characterise the safety and tolerability of the combination of clofarabine (Clolar®) and DaunoXome® including identification of the dose limiting toxicities
2. To document the overall response rate, including complete remission (CR), complete remission with incomplete blood count recovery (CRI) and partial remission (PR) in this population
3. To describe the durability of response and follow up of these patients, including the number of patients that undergo stem-cell transplant after re-induction with clofarabine (Clolar®) and DaunoXome®

Measured as follows:

1. The nature, incidence and severity of the adverse events, collected throughout cycle 1 of therapy
2. Responses measured by bone marrow assessment between day 21 and 42 post first dose of clofarabine (Clolar®) and DaunoXome®

Completion date

30/06/2011

Eligibility

Key inclusion criteria

1. Diagnosis of acute myelogenous leukaemia (AML)
2. Patients must be in first relapse within 12 months of initial diagnosis or refractory to induction therapy or be in second or subsequent relapse
3. Patients with refractory AML following induction must be greater than 20% blasts in the bone marrow
4. Age must be between 6 months to less than 18 years old, either sex
5. Karnofsky or Lansky score of greater than 50
6. Patients of childbearing potential must have a negative pregnancy test and agree to use an effective birth control or evidence of post-menopausal status. Post-menopausal status is defined as either radiation-induced oophorectomy with last menses greater than 1 year ago; chemotherapy induced menopause with 1 year interval since last menses.
7. Normal renal function
8. Normal hepatic function
9. Cardiac function defined as: shortening fraction of greater than 29% by echocardiogram left ventricular ejection fraction (LVEF) greater than 58%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Upper age limit

18 Years

Sex

All

Key exclusion criteria

1. First relapse greater than 1 year from their initial diagnosis of AML
2. Patients whose previous daunorubicin equivalent exposure equals or exceeds 450 mg/m²
3. Isolated extramedullary leukaemia
4. Symptomatic central nervous system (CNS) involvement
5. Any evidence of severe or uncontrolled systemic conditions
6. Concurrent treatment or administration of any other experimental drug or with any other cancer therapy
7. Patients unable to be regularly followed up
8. Patient with expected non-compliance to toxicity management guidelines

Date of first enrolment

01/01/2009

Date of final enrolment

30/06/2011

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Institute of Child Health

Birmingham

United Kingdom

B6 6NH

Sponsor information**Organisation**

University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Charity

Funder Name

Leukaemia Research Fund (UK)

Results and Publications

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?
HRA research summary			28/06/2023	No	No