

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

<b>Submission date</b> 21/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/03/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Study design**

Multicentre prospective non blinded open label phase I dose escalation study

**Primary study design**

Interventional

**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/m<sup>2</sup>. 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/m<sup>2</sup>/day x 5 days

Level 0: 30 mg/m<sup>2</sup>/day/ x 5 days

Level 1: 40 mg/m<sup>2</sup>/day x 5 days

Dose escalation will be capped at 40 mg/m<sup>2</sup>/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/m<sup>2</sup>
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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes