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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
21/10/2008		[_] Protocol		
Registration date 05/02/2009	<b>Overall study status</b> Completed	[] Statistical analysis plan		
		[_] Results		
Last Edited 15/03/2017	<b>Condition category</b> 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-childrenand-teenagers-with-acute-myeloid-leukaemia-cloud

## **Contact information**

**Type(s)** Scientific

Contact name

Dr Pam Kearns

### **Contact details**

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

**Participant information sheet** Not available in web format, please use the contact details below to request a patient information sheet

### 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^2. 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^2/day x 5 days Level 0: 30 mg/m^2/day/ x 5 days Level 1: 40 mg/m^2/day x 5 days

Dose escalation will be capped at 40 mg/m^2/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 measure

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.

### Secondary outcome measures

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 fo 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®

### Overall study start date

01/01/2009

**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

### Age group

Child

### Lower age limit

6 Months

### Upper age limit

18 Years

Sex

Both

### Target number of participants

12 - 18 patients

### 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^2
- 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** England

United Kingdom

**Study participating centre Institute of Child Health** Birmingham United Kingdom B6 6NH

### Sponsor information

**Organisation** University of Birmingham (UK)

**Sponsor details** Research & Commercial Services Aitchison Building Edgbaston Birmingham England United Kingdom B15 2TT

**Sponsor type** University/education

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

ROR https://ror.org/03angcq70

### Funder(s)

Funder type Charity

**Funder Name** Leukaemia Research Fund (UK)

# **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?
HRA research summary			28/06/2023	No	No