ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 03/30/2015

ClinicalTrials.gov ID: NCT00924443

Study Identification

Unique Protocol ID: BIOV-121

Brief Title: A Study of Clofarabine in Older Patients With Acute Myeloid Leukemia (AML) for Whom Chemotherapy Is Not Suitable

Official Title: A Phase II Trial of Clofarabine in Older Patients With Acute Myeloid Leukemia for Whom Intensive Chemotherapy is Not Considered Suitable

Secondary IDs:

Study Status

Record Verification: March 2015

Overall Status: Completed

Study Start: June 2004

Primary Completion: June 2006 [Actual]

Study Completion: March 2008 [Actual]

Sponsor/Collaborators

Sponsor: Genzyme, a Sanofi Company

Responsible Party: Sponsor

Collaborators: Bioenvision

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board:	Approval Status: Approved Approval Number: MREC/03/7/088 Board Name: West Midlands Multi-centre Research Ethics Committee Board Affiliation: National Healthcare System, United Kingdom Phone: 441212452544 Email:
Data Monitoring?:	No
Oversight Authorities:	United Kingdom: Medicines and Healthcare Products Regulatory Agency Ireland: Irish Medicines Board Italy: Ministry of Health

Study Description

Brief Summary:	The purpose of the study is to determine if treatment of older patients indicated with untreated Acute Myeloid Leukemia (AML) who are not considered to be suitable for intensive chemotherapy, can effectively be treated with Clofarabine.
Detailed Description:	Note: This clinical trial was conducted by Bioenvision Ltd. Bioenvision Ltd. was acquired by Genzyme Corporation Oct 2007.

Conditions

Conditions:	Acute Myeloid Leukemia
Keywords:	acute myelogenous leukemia acute myeloid leukemia clolar evoltra clofarabine untreated acute leukemia adult acute leukemia

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label

Allocation: N/A

Endpoint Classification: Safety/Efficacy Study

Enrollment: 69 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Clofarabine Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days (one cycle), then 20mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for the second and subsequent cycles, up to a maximum of 3 cycles.	Drug: clofarabine Other Names: • tradename US = Clolar • tradename EU = Evoltra

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 65 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Provide signed, written informed consent
- Have untreated AML according to World Health Organization (WHO) classification
- Male or post-menopausal female ≥ 65 years of age
- Unsuitable for intensive chemotherapy
- Be able to comply with study procedures and follow-up examination
- Male patient who are fertile agree to use and effective barrier method of birth control to avoid pregnancies
- Have adequate liver and renal function as indicated by certain laboratory values

Exclusion Criteria:

- Received previous treatment with clofarabine
- Are receiving other chemotherapy or corticosteroids (low-dose corticosteroid for pre-medication purposes are allowed)

- Have received prior treatment for leukemia. Growth factor, cytokine support, leukopheresis or hydroxyurea will be allowed but must be discontinued at least 24 hours prior to start of treatment with clofarabine
- Have a psychiatric disorder that would interfere with consent, study participation, or follow-up
- Have an active, uncontrolled systemic infection
- Are currently participating in other investigational drug studies or having received other investigational drugs within the previous 30 days
- Have symptomatic central nervous system (CNS) involvement
- Blast transformation of chronic myeloid leukemia or acute promyelocytic leukemia

Contacts/Locations

Study Officials: Medical Monitor
Genzyme Corporation

Locations: United Kingdom
Cardiff, United Kingdom

Italy
Bologna, Italy

Ireland
Dublin, Ireland

United Kingdom
Nottingham, United Kingdom

Aberdeen, United Kingdom

Manchester, United Kingdom

Birmingham, United Kingdom

Liverpool, United Kingdom

Taunton, United Kingdom

Belfast, Northern Ireland, United Kingdom

Leicester, United Kingdom

Edinburgh, United Kingdom

London, United Kingdom

Italy

Rome, Italy

United Kingdom
Somerset, United Kingdom

References

Citations:

Links:

Study Results

Participant Flow

Recruitment Details	Participants were entered into the study between 14 Jun 2004 and 14 Nov 2005. Participants were recruited from 14 of a total of 17 registered centres located in the United Kingdom (UK), Ireland and Italy. Relapse and survival data follow-up cut-off was extended to 23 May 2008.
Pre-Assignment Details	A total of 69 participants were screened and enrolled. A total of 66 participants received study drug and are included in the reported results.

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days

Overall Study

	Clofarabine
Started	69
Full Analysis Set (Received Study Drug)	66
Completed	66
Not Completed	3
Physician Decision	2
Protocol Violation	1

Baseline Characteristics

Analysis Population Description

Baseline Characteristics provided for Full Analysis Set (FAS) population, defined as all participants with a confirmed diagnosis of AML who received at least one dose of clofarabine

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days (one cycle), then 20mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for the second and subsequent cycles, up to a maximum of 3 cycles.

Baseline Measures

	Clofarabine
Number of Participants	66
Age, Continuous [units: years] Mean (Standard Deviation)	71.5 (4.65)
Gender, Male/Female [units: participants]	
Female	33
Male	33
Race (NIH/OMB) [units: participants]	
American Indian or Alaska Native	0
Asian	0
Native Hawaiian or Other Pacific Islander	0
Black or African American	0
White	66
More than one race	0
Unknown or Not Reported	0

	Clofarabine
Region of Enrollment [units: participants]	
Ireland	3
Italy	8
United Kingdom	55
Cytogenetics (1998) [1] [units: participants]	
Favourable	0
Intermediate	43
Adverse	19
Missing/Unknown	4
Cytogenetics (2001) [2] [units: participants]	
Favourable	0
Intermediate	48
Adverse	14
Missing/Unknown	4
Type of Acute Myeloid Leukemia (AML) [units: participants]	
De Novo	48
Secondary	16
Missing/Unknown	2
White Blood Cell Count (10^9/L) [units: participants]	
<25	57
25-99.9	6
>=100	3

	Clofarabine
Glomerular Filtration Rate (mL/min/1.73m^2) [units: participants]	
<=50	15
>50	51
Number of Co-morbidities [units: participants]	
0	17
1	23
>1	26
Karnofsky Performance Status [3] [units: participants]	
100%	8
90%	13
80%	24
70%	9
60%	2
50%	5
20%	2
Missing	3

[1] Diagnostic criteria of Grimwade for younger patients

[2] Diagnostic criteria of Grimwade for older patients

[3] Karnofsky performance scale is used by doctors to classify patient's functional impairment level. The lower the number the higher the impairment in typical daily activities by the disease.

Typical classification examples: 100% normal with no evidence of disease, 90% able to carry on normal activity with minor signs of illness, 80% normal activity but requiring effort, 70% able to care for self but unable to work or carry on other normal activities, 60% able to care for most needs but requires occasional assistance, 50% considerable assistance and frequent medical care required, etc..

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Overall Response Rate (ORR)
Measure Description	ORR rate was defined as the sum of the number of participants in the study population with complete remission (CR), complete remission with incomplete blood count recovery (CRi), or partial remission (PR) divided by the total number of participants in the study population. ORR rate was determined by assessment of morphology and blast count from bone marrow aspirates and peripheral blood performed prior to first dose and at the end of clofarabine treatment. The ORR was determined at the end of each cycle of clofarabine, and assessed using the participant's best response to clofarabine treatment.
Time Frame	At month 20
Safety Issue?	No

Analysis Population Description

The efficacy analysis was performed on the primary analysis population, the Full Analysis Set population, which consisted of all participants with a diagnosis of AML confirmed by the Investigator who received at least one dose (partial or complete) of clofarabine.

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days (one cycle), then 20mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for the second and subsequent cycles, up to a maximum of 3 cycles.

Measured Values

	Clofarabine
Number of Participants Analyzed	66
Overall Response Rate (ORR) [units: percentage of participants] Number (95% Confidence Interval)	48 (36 to 61)

2. Secondary Outcome Measure:

Measure Title	Rate of Response (Complete, Complete With Incomplete Blood Count Recovery, Partial)

Measure Description	Response was determined by assessment of morphology and blast count from bone marrow aspirates and peripheral blood performed prior to first dose and at the end of clofarabine treatment. Response was determined at the end of each cycle of clofarabine, and assessed using the participant's best response to clofarabine treatment.
Time Frame	At month 20
Safety Issue?	No

Analysis Population Description

The efficacy analyses were performed on the primary analysis population, the Full Analysis Set population, which consisted of all participants with a diagnosis of AML confirmed by the Investigator who received at least one dose (partial or complete) of clofarabine.

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days (one cycle), then 20mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for the second and subsequent cycles, up to a maximum of 3 cycles.

Measured Values

	Clofarabine
Number of Participants Analyzed	66
Rate of Response (Complete, Complete With Incomplete Blood Count Recovery, Partial) [units: percent of participants] Number (95% Confidence Interval)	
Complete response	21 (12 to 33)
Complete with incomplete blood count recovery	23 (13 to 35)
Partial response	5 (1 to 13)

3. Secondary Outcome Measure:

Measure Title	Duration of Overall Response
Measure Description	Duration was calculated by Kaplan-Meier estimates
Time Frame	From 20 months up to 48 months
Safety Issue?	No

Analysis Population Description

The analysis were performed on the primary analysis population, the Full Analysis Set population. Defined as the median duration of overall response (CR +CRi+PR) in participants who achieved CR, CRi or PR only

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days (one cycle), then 20mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for the second and subsequent cycles, up to a maximum of 3 cycles.

Measured Values

	Clofarabine
Number of Participants Analyzed	32
Duration of Overall Response [units: days] Median (95% Confidence Interval)	62 (42 to 153)

4. Secondary Outcome Measure:

Measure Title	Overall Survival
Measure Description	Calculated by Kaplan-Meier estimates
Time Frame	From 20 months up to 48 months
Safety Issue?	No

Analysis Population Description

The efficacy analyses were performed on the primary analysis population, the Full Analysis Set population, which consisted of all participants with a diagnosis of AML confirmed by the Investigator who received at least one dose (partial or complete) of clofarabine.

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days (one cycle), then 20mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for the second and subsequent cycles, up to a maximum of 3 cycles.

Measured Values

	Clofarabine
Number of Participants Analyzed	66
Overall Survival [units: days] Median (95% Confidence Interval)	173 (90 to 295)

5. Secondary Outcome Measure:

Measure Title	Duration of Complete Remission
Measure Description	Duration was calculated by Kaplan- Meier estimates
Time Frame	From 20 months up to 48 months
Safety Issue?	No

Analysis Population Description

The analysis were performed on the primary analysis population, the Full Analysis Set population. Defined as the median duration of participants who achieved CR+CRi only

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days (one cycle), then 20mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for the second and subsequent cycles, up to a maximum of 3 cycles.

Measured Values

	Clofarabine
Number of Participants Analyzed	29
Duration of Complete Remission [units: days] Median (95% Confidence Interval)	63 (43 to 168)

Reported Adverse Events

Time Frame	From first dose until 30 days after study completion (20 months)
Additional Description	In the event a single participant has experienced both a serious and a non-serious form of the same adverse event term, the individual has been included in the numerator (""number of affected participants"") of both adverse event tables.

Reporting Groups

	Description
Clofarabine	Clofarabine 30 mg/m^2/day intravenously over 1 hour for 5 days every 28 to 42 days(one cycle) and 20 mg/m^2/day intravenously over 1 hour for 5 days every 29 to 43 days for second and subsequent cycles,up to a maximum of 3 cycles.

Serious Adverse Events

	Clofarabine
	Affected/At Risk (%)
Total	40/66 (60.61%)
Blood and lymphatic system disorders	
ANAEMIA [A] †	1/66 (1.52%)
FEBRILE NEUTROPENIA [A] †	1/66 (1.52%)
NEUTROPENIA [A] †	1/66 (1.52%)
PANCYTOPENIA [A] †	1/66 (1.52%)
PLATELET DISORDER [A] †	1/66 (1.52%)
Cardiac disorders	
ATRIAL FIBRILLATION [A] †	4/66 (6.06%)
PERICARDIAL EFFUSION [A] †	1/66 (1.52%)
Endocrine disorders	
HYPOPITUITARISM [A] †	1/66 (1.52%)
Gastrointestinal disorders	
ABDOMINAL DISTENSION [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
DIARRHOEA [A] †	2/66 (3.03%)
GASTROINTESTINAL HAEMORRHAGE [A] †	1/66 (1.52%)
ILEUS PARALYTIC [A] †	1/66 (1.52%)
VOMITING [A] †	2/66 (3.03%)
General disorders	
DISEASE PROGRESSION [A] †	1/66 (1.52%)
OEDEMA [A] †	1/66 (1.52%)
PYREXIA [A] †	2/66 (3.03%)
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME [A] †	1/66 (1.52%)
Infections and infestations	
BACTERAEMIA [A] †	1/66 (1.52%)
BRONCHOPNEUMONIA [A] †	1/66 (1.52%)
CATHETER RELATED INFECTION [A] †	1/66 (1.52%)
CENTRAL LINE INFECTION [A] †	1/66 (1.52%)
ENCEPHALITIS HERPES [A] †	1/66 (1.52%)
INFECTION [A] †	2/66 (3.03%)
LOWER RESPIRATORY TRACT INFECTION [A] †	2/66 (3.03%)
NEUTROPENIC SEPSIS [A] †	17/66 (25.76%)
PNEUMONIA [A] †	4/66 (6.06%)
RESPIRATORY TRACT INFECTION FUNGAL [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
SEPSIS [A] †	5/66 (7.58%)
Injury, poisoning and procedural complications	
ACCIDENTAL OVERDOSE [A] †	1/66 (1.52%)
FALL [A] †	1/66 (1.52%)
Investigations	
BLOOD BILIRUBIN INCREASED [A] †	1/66 (1.52%)
BLOOD CREATININE INCREASED [A] †	1/66 (1.52%)
HAEMOGLOBIN DECREASED [A] †	1/66 (1.52%)
HEPATIC ENZYME INCREASED [A] †	1/66 (1.52%)
URINE OUTPUT DECREASED [A] †	2/66 (3.03%)
Metabolism and nutrition disorders	
HYPOKALAEMIA [A] †	2/66 (3.03%)
HYPOMAGNESAEMIA [A] †	1/66 (1.52%)
Musculoskeletal and connective tissue disorders	
BACK PAIN [A] †	1/66 (1.52%)
PAIN IN EXTREMITY [A] †	1/66 (1.52%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
PITUITARY TUMOUR [A] †	1/66 (1.52%)
Nervous system disorders	
CEREBRAL HAEMORRHAGE [A] †	1/66 (1.52%)
CEREBROVASCULAR ACCIDENT [A] †	2/66 (3.03%)
HAEMORRHAGE INTRACRANIAL [A] †	3/66 (4.55%)
HEADACHE [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
SYNCOPE [A] †	1/66 (1.52%)
UNRESPONSIVE TO PAIN STIMULI [A] †	1/66 (1.52%)
Renal and urinary disorders	
NEPHROTIC SYNDROME [A] †	1/66 (1.52%)
RENAL FAILURE ACUTE [A] †	7/66 (10.61%)
RENAL IMPAIRMENT [A] †	2/66 (3.03%)
RENAL INSUFFICIENCY [A] †	5/66 (7.58%)
Skin and subcutaneous tissue disorders	
RASH [A] †	2/66 (3.03%)
SKIN DESQUAMATION [A] †	1/66 (1.52%)
Vascular disorders	
HYPOTENSION [A] †	1/66 (1.52%)
THROMBOSIS [A] †	1/66 (1.52%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 16.1

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Clofarabine
	Affected/At Risk (%)
Total	66/66 (100%)
Blood and lymphatic system disorders	
ANAEMIA [A] †	22/66 (33.33%)
COAGULOPATHY [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
DISSEMINATED INTRAVASCULAR COAGULATION [A] †	1/66 (1.52%)
FEBRILE NEUTROPENIA [A] †	4/66 (6.06%)
HAEMOLYTIC ANAEMIA [A] †	1/66 (1.52%)
LYMPHOPENIA [A] †	2/66 (3.03%)
NEUTROPENIA [A] †	19/66 (28.79%)
PANCYTOPENIA [A] †	1/66 (1.52%)
SPLENOMEGALY [A] †	1/66 (1.52%)
THROMBOCYTOPENIA [A] †	32/66 (48.48%)
Cardiac disorders	
ARRHYTHMIA SUPRAVENTRICULAR [A] †	2/66 (3.03%)
ATRIAL FIBRILLATION [A] †	4/66 (6.06%)
PALPITATIONS [A] †	1/66 (1.52%)
SUPRAVENTRICULAR EXTRASYSTOLES [A] †	1/66 (1.52%)
TACHYCARDIA [A] †	1/66 (1.52%)
Ear and labyrinth disorders	
VERTIGO [A] †	1/66 (1.52%)
Endocrine disorders	
ADRENAL INSUFFICIENCY [A] †	1/66 (1.52%)
HYPOTHALAMO-PITUITARY DISORDERS [A] †	1/66 (1.52%)
HYPOTHYROIDISM [A] †	1/66 (1.52%)
Eye disorders	

	Clofarabine
	Affected/At Risk (%)
EYE PAIN [A] †	1/66 (1.52%)
EYE REDNESS [A] †	1/66 (1.52%)
HETEROPHORIA [A] †	1/66 (1.52%)
KERATOCONJUNCTIVITIS SICCA [A] †	2/66 (3.03%)
LACRIMATION INCREASED [A] †	1/66 (1.52%)
VISION BLURRED [A] †	2/66 (3.03%)
Gastrointestinal disorders	
ABDOMINAL DISTENSION [A] †	1/66 (1.52%)
ABDOMINAL PAIN [A] †	13/66 (19.7%)
CHEILITIS [A] †	1/66 (1.52%)
CONSTIPATION [A] †	27/66 (40.91%)
DIARRHOEA [A] †	40/66 (60.61%)
DRY MOUTH [A] †	6/66 (9.09%)
DYSPEPSIA [A] †	5/66 (7.58%)
DYSPHAGIA [A] †	1/66 (1.52%)
ERUCTATION [A] †	1/66 (1.52%)
FAECALOMA [A] †	1/66 (1.52%)
FLATULENCE [A] †	1/66 (1.52%)
GASTROINTESTINAL HAEMORRHAGE [A] †	1/66 (1.52%)
GINGIVAL PAIN [A] †	1/66 (1.52%)
GLOSSODYNIA [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
HAEMATEMESIS [A] †	1/66 (1.52%)
HAEMORRHOIDAL HAEMORRHAGE [A] †	1/66 (1.52%)
ILEUS PARALYTIC [A] †	1/66 (1.52%)
LOOSE STOOLS [A] †	2/66 (3.03%)
MELAENA [A] †	2/66 (3.03%)
MOUTH ULCERATION [A] †	6/66 (9.09%)
NAUSEA [A] †	44/66 (66.67%)
OESOPHAGEAL ULCER [A] †	1/66 (1.52%)
ORAL MUCOSAL BLISTERING [A] †	1/66 (1.52%)
ORAL MUCOSAL PETECHIAE [A] †	1/66 (1.52%)
ORAL PAIN [A] †	5/66 (7.58%)
RECTAL PROLAPSE [A] †	1/66 (1.52%)
STOMATITIS [A] †	5/66 (7.58%)
SWOLLEN TONGUE [A] †	1/66 (1.52%)
TONGUE BLISTERING [A] †	1/66 (1.52%)
TONGUE COATED [A] †	3/66 (4.55%)
TONGUE ULCERATION [A] †	1/66 (1.52%)
TOOTHACHE [A] †	2/66 (3.03%)
VOMITING [A] †	37/66 (56.06%)
General disorders	
ASTHENIA [A] †	7/66 (10.61%)

	Clofarabine
	Affected/At Risk (%)
CATHETER RELATED COMPLICATION [A] †	14/66 (21.21%)
CATHETER SITE INFLAMMATION [A] †	1/66 (1.52%)
CHEST DISCOMFORT [A] †	1/66 (1.52%)
CHEST PAIN [A] †	11/66 (16.67%)
FATIGUE [A] †	16/66 (24.24%)
GAIT ABNORMAL [A] †	2/66 (3.03%)
GENERALISED OEDEMA [A] †	1/66 (1.52%)
INFLUENZA LIKE ILLNESS [A] †	2/66 (3.03%)
LOCALISED OEDEMA [A] †	1/66 (1.52%)
MASS [A] †	1/66 (1.52%)
MUCOSAL INFLAMMATION [A] †	2/66 (3.03%)
OEDEMA [A] †	2/66 (3.03%)
OEDEMA PERIPHERAL [A] †	12/66 (18.18%)
PAIN [A] †	3/66 (4.55%)
PITTING OEDEMA [A] †	1/66 (1.52%)
PYREXIA [A] †	24/66 (36.36%)
RIGORS [A] †	7/66 (10.61%)
TENDERNESS [A] †	1/66 (1.52%)
Hepatobiliary disorders	
CHOLELITHIASIS [A] †	1/66 (1.52%)
HEPATOTOXICITY [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
HYPERBILIRUBINAEMIA [A] †	4/66 (6.06%)
Immune system disorders	
HYPERSENSITIVITY [A] †	2/66 (3.03%)
Infections and infestations	
ANAL INFECTION [A] †	1/66 (1.52%)
BACTERIAL INFECTION [A] †	2/66 (3.03%)
BACTERIAL SEPSIS [A] †	2/66 (3.03%)
CELLULITIS [A] †	7/66 (10.61%)
CENTRAL LINE INFECTION [A] †	11/66 (16.67%)
CLOSTRIDIAL INFECTION [A] †	1/66 (1.52%)
CLOSTRIDIUM COLITIS [A] †	1/66 (1.52%)
FUNGAL INFECTION [A] †	1/66 (1.52%)
GASTROINTESTINAL CANDIDIASIS [A] †	1/66 (1.52%)
GENITAL INFECTION FEMALE [A] †	1/66 (1.52%)
HERPES SIMPLEX [A] †	3/66 (4.55%)
HERPES VIRUS INFECTION [A] †	1/66 (1.52%)
INFECTION [A] †	9/66 (13.64%)
LOWER RESPIRATORY TRACT INFECTION [A] †	4/66 (6.06%)
NASOPHARYNGITIS [A] †	1/66 (1.52%)
NEUTROPENIC INFECTION [A] †	2/66 (3.03%)
NEUTROPENIC SEPSIS [A] †	3/66 (4.55%)
ORAL CANDIDIASIS [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
PHARYNGITIS [A] †	1/66 (1.52%)
PNEUMONIA [A] †	3/66 (4.55%)
PNEUMONIA FUNGAL [A] †	2/66 (3.03%)
RHINITIS [A] †	1/66 (1.52%)
SEPSIS [A] †	5/66 (7.58%)
URINARY TRACT INFECTION [A] †	2/66 (3.03%)
VANCOMYCIN-RESISTANT ENTEROCOCCAL INFECTION [A] †	1/66 (1.52%)
VIRAL INFECTION [A] †	2/66 (3.03%)
Injury, poisoning and procedural complications	
BLISTER [A] †	1/66 (1.52%)
CONTUSION [A] †	4/66 (6.06%)
FALL [A] †	3/66 (4.55%)
MEDICAL DEVICE DISCOMFORT [A] †	1/66 (1.52%)
TRANSFUSION REACTION [A] †	3/66 (4.55%)
Investigations	
ACTIVATED PARTIAL THROMBOPLASTIN TIME PROLONGED [A] †	1/66 (1.52%)
ALANINE AMINOTRANSFERASE INCREASED [A] †	21/66 (31.82%)
ASPARTATE AMINOTRANSFERASE INCREASED [A] †	15/66 (22.73%)
BACTERIA BLOOD IDENTIFIED [A] †	1/66 (1.52%)
BACTERIA STOOL IDENTIFIED [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
BLOOD ALBUMIN DECREASED [A] †	2/66 (3.03%)
BLOOD ALKALINE PHOSPHATASE INCREASED [A] †	5/66 (7.58%)
BLOOD BICARBONATE DECREASED [A] †	4/66 (6.06%)
BLOOD BILIRUBIN INCREASED [A] †	6/66 (9.09%)
BLOOD CALCIUM DECREASED [A] †	3/66 (4.55%)
BLOOD CREATININE [A] †	1/66 (1.52%)
BLOOD CREATININE ABNORMAL [A] †	2/66 (3.03%)
BLOOD CREATININE DECREASED [A] †	1/66 (1.52%)
BLOOD CREATININE INCREASED [A] †	8/66 (12.12%)
BLOOD LACTATE DEHYDROGENASE INCREASED [A] †	9/66 (13.64%)
BLOOD MAGNESIUM [A] †	1/66 (1.52%)
BLOOD MAGNESIUM DECREASED [A] †	2/66 (3.03%)
BLOOD MAGNESIUM INCREASED [A] †	2/66 (3.03%)
BLOOD PHOSPHORUS DECREASED [A] †	3/66 (4.55%)
BLOOD PHOSPHORUS INCREASED [A] †	1/66 (1.52%)
BLOOD POTASSIUM DECREASED [A] †	11/66 (16.67%)
BLOOD PRESSURE DECREASED [A] †	1/66 (1.52%)
BLOOD SODIUM DECREASED [A] †	3/66 (4.55%)
BLOOD SODIUM INCREASED [A] †	1/66 (1.52%)
BLOOD UREA DECREASED [A] †	1/66 (1.52%)
BLOOD UREA INCREASED [A] †	10/66 (15.15%)

	Clofarabine
	Affected/At Risk (%)
BODY TEMPERATURE INCREASED [A] †	1/66 (1.52%)
CARDIAC MURMUR [A] †	1/66 (1.52%)
HAEMOGLOBIN DECREASED [A] †	6/66 (9.09%)
HEART RATE IRREGULAR [A] †	1/66 (1.52%)
HEPATIC ENZYME INCREASED [A] †	1/66 (1.52%)
LIVER FUNCTION TEST ABNORMAL [A] †	3/66 (4.55%)
NEUTROPHIL COUNT DECREASED [A] †	1/66 (1.52%)
PLATELET COUNT DECREASED [A] †	6/66 (9.09%)
PROTEIN TOTAL DECREASED [A] †	2/66 (3.03%)
PROTHROMBIN TIME PROLONGED [A] †	1/66 (1.52%)
TROPONIN T INCREASED [A] †	1/66 (1.52%)
URINE OUTPUT DECREASED [A] †	1/66 (1.52%)
WEIGHT DECREASED [A] †	3/66 (4.55%)
WEIGHT INCREASED [A] †	4/66 (6.06%)
WHITE BLOOD CELL COUNT DECREASED [A] †	2/66 (3.03%)
Metabolism and nutrition disorders	
ACIDOSIS [A] †	2/66 (3.03%)
ANOREXIA [A] †	10/66 (15.15%)
DECREASED APPETITE [A] †	17/66 (25.76%)
DEHYDRATION [A] †	5/66 (7.58%)
ELECTROLYTE IMBALANCE [A] †	2/66 (3.03%)

	Clofarabine
	Affected/At Risk (%)
FLUID OVERLOAD [A] †	2/66 (3.03%)
GOUT [A] †	2/66 (3.03%)
HYPERGLYCAEMIA [A] †	4/66 (6.06%)
HYPERNATRAEMIA [A] †	1/66 (1.52%)
HYPERPHOSPHATAEMIA [A] †	1/66 (1.52%)
HYPOALBUMINAEMIA [A] †	6/66 (9.09%)
HYPOCALCAEMIA [A] †	11/66 (16.67%)
HYPOKALAEMIA [A] †	23/66 (34.85%)
HYPOMAGNESAEMIA [A] †	4/66 (6.06%)
HYPONATRAEMIA [A] †	3/66 (4.55%)
HYPOPHOSPHATAEMIA [A] †	3/66 (4.55%)
METABOLIC ACIDOSIS [A] †	1/66 (1.52%)
Musculoskeletal and connective tissue disorders	
ARTHRALGIA [A] †	7/66 (10.61%)
ARTHRITIS [A] †	1/66 (1.52%)
BACK PAIN [A] †	6/66 (9.09%)
BUTTOCK PAIN [A] †	1/66 (1.52%)
JOINT STIFFNESS [A] †	1/66 (1.52%)
JOINT SWELLING [A] †	2/66 (3.03%)
MUSCLE CRAMP [A] †	1/66 (1.52%)
MUSCULOSKELETAL PAIN [A] †	1/66 (1.52%)
MYALGIA [A] †	5/66 (7.58%)

	Clofarabine
	Affected/At Risk (%)
NECK PAIN [A] †	1/66 (1.52%)
PAIN IN EXTREMITY [A] †	7/66 (10.61%)
Nervous system disorders	
BURNING SENSATION [A] †	2/66 (3.03%)
CENTRAL NERVOUS SYSTEM INFLAMMATION [A] †	1/66 (1.52%)
CEREBRAL ISCHAEMIA [A] †	1/66 (1.52%)
DEPRESSED LEVEL OF CONSCIOUSNESS [A] †	1/66 (1.52%)
DIZZINESS [A] †	11/66 (16.67%)
DYSARTHRIA [A] †	1/66 (1.52%)
DYSGEUSIA [A] †	3/66 (4.55%)
HAEMORRHAGE INTRACRANIAL [A] †	1/66 (1.52%)
HEADACHE [A] †	14/66 (21.21%)
HYPERAESTHESIA [A] †	1/66 (1.52%)
HYPOAESTHESIA [A] †	1/66 (1.52%)
LETHARGY [A] †	7/66 (10.61%)
PARAESTHESIA [A] †	1/66 (1.52%)
POLYNEUROPATHY [A] †	1/66 (1.52%)
RESTLESS LEGS SYNDROME [A] †	1/66 (1.52%)
SOMNOLENCE [A] †	1/66 (1.52%)
SPEECH DISORDER [A] †	1/66 (1.52%)
SYNCOPE [A] †	3/66 (4.55%)

	Clofarabine
	Affected/At Risk (%)
SYNCOPE VASOVAGAL [A] †	3/66 (4.55%)
TRANSIENT ISCHAEMIC ATTACK [A] †	1/66 (1.52%)
Psychiatric disorders	
AGITATION [A] †	5/66 (7.58%)
ANXIETY [A] †	7/66 (10.61%)
CONFUSIONAL STATE [A] †	9/66 (13.64%)
DEPRESSED MOOD [A] †	1/66 (1.52%)
DEPRESSION [A] †	2/66 (3.03%)
DISORIENTATION [A] †	1/66 (1.52%)
EMOTIONAL DISTRESS [A] †	1/66 (1.52%)
HALLUCINATION [A] †	6/66 (9.09%)
INSOMNIA [A] †	9/66 (13.64%)
PANIC ATTACK [A] †	1/66 (1.52%)
PSYCHIATRIC SYMPTOM [A] †	1/66 (1.52%)
SLEEP DISORDER [A] †	1/66 (1.52%)
Renal and urinary disorders	
DYSURIA [A] †	2/66 (3.03%)
HAEMATURIA [A] †	5/66 (7.58%)
OLIGURIA [A] †	1/66 (1.52%)
POLLAKIURIA [A] †	1/66 (1.52%)
RENAL COLIC [A] †	1/66 (1.52%)
RENAL FAILURE ACUTE [A] †	3/66 (4.55%)

	Clofarabine
	Affected/At Risk (%)
RENAL IMPAIRMENT [A] †	7/66 (10.61%)
RENAL INSUFFICIENCY [A] †	2/66 (3.03%)
RENAL TUBULAR DISORDER [A] †	1/66 (1.52%)
URINARY INCONTINENCE [A] †	4/66 (6.06%)
Reproductive system and breast disorders	
BALANITIS [A] †	1/66 (1.52%)
PENIS DISORDER [A] †	1/66 (1.52%)
VAGINAL HAEMORRHAGE [A] †	1/66 (1.52%)
Respiratory, thoracic and mediastinal disorders	
APNOEIC ATTACK [A] †	1/66 (1.52%)
CAPILLARY LEAK SYNDROME [A] †	2/66 (3.03%)
COUGH [A] †	13/66 (19.7%)
CRACKLES LUNG [A] †	2/66 (3.03%)
DYSPNOEA [A] †	14/66 (21.21%)
DYSPNOEA EXERTIONAL [A] †	1/66 (1.52%)
EPISTAXIS [A] †	8/66 (12.12%)
HAEMOPTYSIS [A] †	1/66 (1.52%)
HYPOXIA [A] †	2/66 (3.03%)
INCREASED UPPER AIRWAY SECRETION [A] †	1/66 (1.52%)
LUNG CREPITATION [A] †	6/66 (9.09%)
LUNG INFILTRATION [A] †	1/66 (1.52%)
NASAL CONGESTION [A] †	1/66 (1.52%)

	Clofarabine
	Affected/At Risk (%)
PHARYNGOLARYNGEAL PAIN [A] †	8/66 (12.12%)
PLEURAL EFFUSION [A] †	6/66 (9.09%)
PLEURITIC PAIN [A] †	3/66 (4.55%)
PNEUMOTHORAX [A] †	1/66 (1.52%)
PRODUCTIVE COUGH [A] †	1/66 (1.52%)
PULMONARY OEDEMA [A] †	2/66 (3.03%)
RESPIRATORY DISORDER [A] †	1/66 (1.52%)
RHINORRHOEA [A] †	2/66 (3.03%)
WHEEZING [A] †	5/66 (7.58%)
Skin and subcutaneous tissue disorders	
ALOPECIA [A] †	1/66 (1.52%)
DECUBITUS ULCER [A] †	3/66 (4.55%)
DERMATITIS ALLERGIC [A] †	1/66 (1.52%)
DERMATITIS EXFOLIATIVE [A] †	1/66 (1.52%)
DRY SKIN [A] †	1/66 (1.52%)
ECCHYMOSIS [A] †	1/66 (1.52%)
ERYTHEMA [A] †	7/66 (10.61%)
HYPERHIDROSIS [A] †	3/66 (4.55%)
LOCALISED SKIN REACTION [A] †	1/66 (1.52%)
NIGHT SWEATS [A] †	1/66 (1.52%)
PALMAR ERYTHEMA [A] †	1/66 (1.52%)
PRURITUS [A] †	7/66 (10.61%)

	Clofarabine
	Affected/At Risk (%)
PRURITUS GENERALISED [A] †	1/66 (1.52%)
PURPURA [A] †	1/66 (1.52%)
RASH [A] †	29/66 (43.94%)
RASH ERYTHEMATOUS [A] †	3/66 (4.55%)
RASH GENERALISED [A] †	1/66 (1.52%)
RASH MACULAR [A] †	1/66 (1.52%)
RASH MACULO-PAPULAR [A] †	1/66 (1.52%)
RASH PAPULAR [A] †	1/66 (1.52%)
RASH PRURITIC [A] †	3/66 (4.55%)
SWELLING FACE [A] †	1/66 (1.52%)
Social circumstances	
INADEQUATE DIET [A] †	1/66 (1.52%)
Vascular disorders	
FLUSHING [A] †	2/66 (3.03%)
HAEMORRHAGE [A] †	2/66 (3.03%)
HYPERTENSION [A] †	7/66 (10.61%)
HYPOTENSION [A] †	11/66 (16.67%)
ORTHOSTATIC HYPOTENSION [A] †	1/66 (1.52%)
PETECHIAE [A] †	5/66 (7.58%)
VENOUS THROMBOSIS LIMB [A] †	1/66 (1.52%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 16.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

There IS an agreement between the Principal Investigator (PI) and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed. In multi-site studies, PI can publish after sponsor publishes or 18 months after study completion. PI gives sponsor a draft 60 days before publication. Sponsor can ask that confidential information be removed, and can defer publication another 60 days upon notifying PI that it will file a patent application.

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