Trial of Decitabine in Patients With Acute Myeloid Leukemia

This study has been completed.

Sponsor:
Eisai Inc.

Information provided by (Responsible Party):
Eisai Inc.

ClinicalTrials.gov Identifier:
NCT00260832

First received: December 1, 2005
Last updated: September 20, 2011
Last verified: September 2011
History of Changes

Results First Received: April 13, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Acute Myeloid Leukemia
Interventions:	Drug: Cytarabine or Supportive Care Drug: Dacogen (decitabine) only

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
This study was recruited at 65 centers in 12 countries during the period of 2006 to 2009.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Prior to randomization, subjects indicated their preference for treatment, with physician's advice, or either cytarabine or supportive care in the event they were randomized to Arm A.

Reporting Groups

	Description
Cytarabine or Supportive Care	Subject's choice of treatment with physician's advice of either supportive care (IV fluids, nutrition, and antibiotics as needed) or cytarabine 20 mg/m^2 given subcutaneously once daily for 10 consecutive days, repeated every 4 weeks. (These represent one intervention.)

Dacogen (Decitabine) Only	20 mg/m^2 Dacogen (decitabine) given as 1-hour infusion once daily for 5 consecutive days every 4 weeks.

Participant Flow: Overall Study

	Cytarabine or Supportive Care	Dacogen (Decitabine) Only
STARTED	243	242
COMPLETED	15 [1]	31 [1]
NOT COMPLETED	228	211
Adverse Event	26	19
Progression	116	96
Withdrawal by Subject	15	17
Physician Decision	15	9
Death	43	62
Not Specified	10	7
Protocol Violation	3	1

[1] At study completion, these subjects chose to remain on treatment

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
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Total	Total of all reporting groups

Baseline Measures

	Cytarabine or Supportive Care	Dacogen (Decitabine) Only	Total
Overall Participants Analyzed [Units: Participants]	243	242	485
Age [Units: Years] Mean (Standard Deviation)	73.53 (5.67)	73.14 (5.24)	73.34 (5.46)
Gender [Units: Participants]			
Female	92	105	197
Male	151	137	288
Race (NIH/OMB)			

[Units: Subjects]			
American Indian or Alaska Native	**0**	**0**	**0**
Asian	**27**	**33**	**60**
Native Hawaiian or Other Pacific Islander	**0**	**0**	**0**
Black or African American	**3**	**0**	**3**
White	**213**	**209**	**422**
More than one race	**0**	**0**	**0**
Unknown or Not Reported	**0**	**0**	**0**

Outcome Measures

1. Primary: Overall Survival in Patients 65 Years or Older Who Have Newly Diagnosed de Novo or Secondary AML. [Time Frame: The interval from date of randomization to the date of death from any cause or the last date the subject was known to be alive or 5 years whichever occurs first.]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Overall Survival in Patients 65 Years or Older Who Have Newly Diagnosed de Novo or Secondary AML.
Measure Description	The interval from date of randomization to the date of death from any cause or the last date the subject was known to be alive or 5 years whichever occurs first.
Time Frame	The interval from date of randomization to the date of death from any cause or the last date the subject was known to be alive or 5 years whichever occurs first.
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The primary population for all efficacy analyses was the Intent-to-treat (ITT) population defined as all subjects randomly allocated to a treatment arm.

Reporting Groups

	Description
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Measured Values

	Cytarabine or Supportive Care	**Dacogen (Decitabine) Only**
Participants Analyzed [Units: Participants]	**243**	**242**
Overall Survival in Patients 65 Years or Older Who Have Newly Diagnosed de Novo or Secondary AML. [Units: Months] Median (Full Range)	**5.0** **(4.3 to 6.3)**	**7.7** **(6.2 to 9.2)**

Statistical Analysis 1 for Overall Survival in Patients 65 Years or Older Who Have Newly Diagnosed de Novo or Secondary AML.

Groups [1]	All groups
Method [2]	Kaplan-Meier
P Value [3]	0.1079

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The primary treatment comparison was based on two sided long-rank test stratified by age, cytogenetic risk, ECOG performance status
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

2. Secondary: Comparison of Complete Remission Rates Between Arm A and Arm B [Time Frame: Post randomization when at least one post-baseline bone marrow assessment or peripheral blood count data available. No stated duration of response required for complete remission classification]

Results not yet reported. Anticipated Reporting Date: No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Cytarabine or Supportive Care	Subject's choice of treatment with physician's advice of either supportive care (IV fluids, nutrition, and antibiotics as needed) or cytarabine 20 mg/m^2 given subcutaneously once daily for 10 consecutive days, repeated every 4 weeks. (These represent one intervention.)
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Serious Adverse Events

	Cytarabine or Supportive Care	Dacogen (Decitabine) Only
Total, serious adverse events		
# participants affected / at risk	**162/237 (68.35%)**	**190/238 (79.83%)**
Blood and lymphatic system disorders		
Febrile Neutropenia		
# participants affected / at risk	**33/237 (13.92%)**	**57/238 (23.95%)**
Thrombocytopenia		
# participants affected / at risk	**11/237 (4.64%)**	**21/238 (8.82%)**
Anemia		
# participants affected / at risk	**12/237 (5.06%)**	**15/238 (6.30%)**

Neutropenia		
# participants affected / at risk	7/237 (2.95%)	15/238 (6.30%)
Cardiac disorders		
Atrial Fibrillation		
# participants affected / at risk	10/237 (4.22%)	4/238 (1.68%)
General disorders		
Disease Progression		
# participants affected / at risk	31/237 (13.08%)	27/238 (11.34%)
Pyrexia		
# participants affected / at risk	20/237 (8.44%)	23/238 (9.66%)
General Physical Health Deterioration		
# participants affected / at risk	14/237 (5.91%)	15/238 (6.30%)
Infections and infestations		
Pneumonia		
# participants affected / at risk	36/237 (15.19%)	48/238 (20.17%)
Sepsis		
# participants affected / at risk	10/237 (4.22%)	15/238 (6.30%)
Septic Shock		
# participants affected / at risk	8/237 (3.38%)	15/238 (6.30%)
Bronchopneumonia		
# participants affected / at risk	12/237 (5.06%)	9/238 (3.78%)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Cytarabine or Supportive Care	Subject's choice of treatment with physician's advice of either supportive care (IV fluids, nutrition, and antibiotics as needed) or cytarabine 20 mg/m^2 given subcutaneously once daily for 10 consecutive days, repeated every 4 weeks. (These represent one intervention.)
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Other Adverse Events

	Cytarabine or Supportive Care	Dacogen (Decitabine) Only
Total, other (not including serious) adverse events		
# participants affected / at risk	231/237 (97.47%)	237/238 (99.58%)
Blood and lymphatic system disorders		
Thrombocytopenia		
# participants affected / at risk	86/237 (36.29%)	106/238 (44.54%)

Anemia		
# participants affected / at risk	73/237 (30.80%)	97/238 (40.76%)
Febrile Neutropenia		
# participants affected / at risk	54/237 (22.78%)	79/238 (33.19%)
General disorders		
Pyrexia		
# participants affected / at risk	88/237 (37.13%)	114/238 (47.90%)
Disease Progression		
# participants affected / at risk	59/237 (24.89%)	55/238 (23.11%)
Peripheral Edema		
# participants affected / at risk	42/237 (17.72%)	50/238 (21.01%)
Infections and infestations		
Pneumonia		
# participants affected / at risk	50/237 (21.10%)	58/238 (24.37%)
Urinary Tract Infection		
# participants affected / at risk	14/237 (5.91%)	35/238 (14.71%)
Oral Herpes		
# participants affected / at risk	16/237 (6.75%)	25/238 (10.50%)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

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

There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Mayer J, Arthur C, Delaunay J, Mazur G, Thomas XG, Wierzbowska A, Ravandi F, Berrak E, Jones M, Li Y, Kantarjian HM. Multivariate and subgroup analyses of a randomized, multinational, phase 3 trial of decitabine vs treatment choice of supportive care or cytarabine in older patients with newly diagnosed acute myeloid leukemia and poor- or intermediate-risk cytogenetics. BMC Cancer. 2014 Feb 6;14:69. doi: 10.1186/1471-2407-14-69.

Responsible Party:	Eisai Inc.
ClinicalTrials.gov Identifier:	NCT00260832 History of Changes
Other Study ID Numbers:	DACO-016
Study First Received:	December 1, 2005
Results First Received:	April 13, 2011
Last Updated:	September 20, 2011
Health Authority:	United States: Food and Drug Administration

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