Purpose

This Phase 3 study assesses two drug regimens as the initial treatment of patients who are at least 70 years of age and have newly diagnosed acute myeloid leukemia (AML) for whom the doctor does not recommend the use of standard intensive treatment or the patient has decided not to receive standard intensive treatment after being fully informed about its benefits and risks by his/her doctor. The two drug regimens are sapacitabine administered in alternating cycles with decitabine, or decitabine alone. The purpose of the study is to learn which drug regimen is more likely to keep AML in check as long as possible.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Myeloid Leukemia</td>
<td>Drug: Sapacitabine and decitabine</td>
<td>Phase 3</td>
</tr>
<tr>
<td></td>
<td>Drug: Decitabine</td>
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</tbody>
</table>

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase III Randomized Study of Oral Sapacitabine in Elderly Patients With Newly Diagnosed Acute Myeloid Leukemia

Resource links provided by NLM:

- Genetics Home Reference related topics: core binding factor acute myeloid leukemia, cytogenetically normal acute myeloid leukemia, familial acute myeloid leukemia with mutated CEBPA
- MedlinePlus related topics: Acute Myeloid Leukemia, Leukemia
- Drug Information available for: Decitabine

U.S. FDA Resources

Further study details as provided by Cyclacel Pharmaceuticals, Inc.
Overall survival [Time Frame: up to 43 months] [Designated as safety issue: Yes]

Secondary Outcome Measures:
- Complete remission with duration [Time Frame: Up to 43 months] [Designated as safety issue: Yes]
- Complete remission with incomplete platelet count recovery and duration [Time Frame: up to 43 months] [Designated as safety issue: Yes]
- Partial remission with duration [Time Frame: up to 43 months] [Designated as safety issue: Yes]
- Hematological improvement with duration [Time Frame: up to 43 months] [Designated as safety issue: Yes]
- Stable disease with duration [Time Frame: up to 43 months] [Designated as safety issue: Yes]
- Number of units of blood product transfused [Time Frame: up to 43 months] [Designated as safety issue: No]
- Hospitalized days [Time Frame: up to 43 months] [Designated as safety issue: Yes]
- 1-year survival [Time Frame: up to 43 months] [Designated as safety issue: Yes]

Estimated Enrollment: 485
Study Start Date: January 2011
Estimated Study Completion Date: April 2015
Estimated Primary Completion Date: October 2014 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: Arm A</td>
<td>Drug: <strong>Sapacitabine</strong> and decitabine</td>
</tr>
<tr>
<td><strong>Sapacitabine</strong> and decitabine</td>
<td><strong>Sapacitabine</strong> administered in alternating cycles with decitabine</td>
</tr>
<tr>
<td>Active Comparator: Arm C</td>
<td>Drug: Decitabine</td>
</tr>
<tr>
<td>Decitabine</td>
<td>Decitabine alone</td>
</tr>
</tbody>
</table>

**Detailed Description:**
This is a multicenter, randomized, Phase 3 study comparing two drug regimens (arms) as the front-line treatment of elderly patients aged 70 years or older with newly diagnosed acute myeloid leukemia (AML) who are not candidates for intensive induction chemotherapy. In Arm A, sapacitabine is administered in alternating cycles with decitabine, and in Arm C decitabine is administered alone. The primary efficacy endpoint is overall survival. The study is designed to demonstrate an improvement in overall survival of Arm A versus Arm C.

**Eligibility**
- Ages Eligible for Study: 70 Years and older
- Genders Eligible for Study: Both
- Accepts Healthy Volunteers: No

**Criteria**
**Inclusion Criteria:**
- Newly diagnosed AML based on WHO classification
- Age 70 years or older for whom the treatment of choice is low-intensity therapy by investigator assessment or who has refused intensive induction therapy recommended by investigator
- ECOG performance status 0-2
- Adequate renal function
- Adequate liver function
- Able to swallow capsules
- Agree to practice effective contraception
- Ability to understand and willingness to sign the informed consent form

**Exclusion Criteria:**
- AML is of the sub-type of acute promyelocytic leukemia or extramedullary myeloid tumor without bone marrow involvement
- Having received any systemic anti-cancer therapy for AML or received treatment with hypomethylating agents or cytotoxic chemotherapy for the preceding MDS or MPD
- Known or suspected central nervous system (CNS) involvement by leukemia
- Uncontrolled intercurrent illness
- Known hypersensitivity to decitabine
Know n to be HIV-positive

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01303796

Contacts

Contact: Judy H Chiao, MD  908-517-7330  jchiao@cyclacel.com

Show 101 Study Locations

Sponsors and Collaborators

Cyclacel Pharmaceuticals, Inc.

Investigators

Study Chair:  Hagop Kantarjian, M.D.  M.D. Anderson Cancer Center

More Information

No publications provided

Responsible Party:  Cyclacel Pharmaceuticals, Inc.
ClinicalTrials.gov Identifier:  NCT01303796  History of Changes
Other Study ID Numbers:  CYC682-12
Study First Received:  February 21, 2011
Last Updated:  September 8, 2014
Health Authority:  United States: Food and Drug Administration

Keywords provided by Cyclacel Pharmaceuticals, Inc.:
AML

Additional relevant MeSH terms:
Leukemia  Antimetabolites
Leukemia, Myeloid  Antimetabolites, Antineoplastic
Leukemia, Myeloid, Acute  Antineoplastic Agents
Neoplasms  Enzyme Inhibitors
Neoplasms by Histologic Type  Molecular Mechanisms of Pharmacological Action
Azacitidine  Pharmacologic Actions
Decitabine  Therapeutic Uses

ClinicalTrials.gov processed this record on November 16, 2014