

Study shows improved survival in aggressive acute myeloid leukemia

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Patients who relapse in their battle with acute myeloid leukemia (AML) may benefit from a phase three study of therapies that combine an existing agent, cytarabine, with a newer compound, vosaroxin.

The study, led by Farhad Ravandi, M.D, professor of medicine, department of leukemia at The University of Texas MD Anderson Cancer Center, demonstrated increased survival rates, particularly in AML patients over age 60.

Ravandi's study results were presented today at the 56th Annual Meeting of the American Society of Hematology (ASH) annual conference in San Francisco and were published in the ASH journal Blood.

Acute myeloid leukemia is the most common form of [adult leukemia](#). The current accepted treatment, cytarabine, when used with other existing agents such as anthracyclines, is associated with increased toxic side effects.

The 124-site international randomized trial was among the largest of its kind. It demonstrated that combination therapy employing the agent cytarabine with others such as vosaroxin does not cause the significant [toxic side effects](#) experienced when cytarabine is used in combination with anthracyclines.

"Currently there are no standard-of-care approved treatments for relapsed or treatment-resistant AML. Effective and safe therapies are

critically needed for patients with relapsed or treatment-resistant [acute myeloid leukemia](#)" said Ravandi. "These data provide encouraging support that this combination may be an effective new salvage therapy in older patients with this challenging condition."

Toxic side effects from combining cytarabine with anthracyclines or topoisomerase inhibitors can include damage to the heart muscle. By combining cytarabine with new agents, researchers hope to develop an effective treatment for AML that does not cause significant additional toxicity. One such agent is vosaroxin, an agent that can target and evade the cancer cell's natural defenses and help induce cancer cell death. Researchers have investigated this compound in a phase three randomized trial to evaluate its ability to overcome the limitations of current therapies without the cardiotoxicities commonly observed with other treatments.

In the trial, 711 patients with relapsed or hard-to-treat AML at 124 sites worldwide were randomized to receive cytarabine with either vosaroxin or placebo. Patients treated with vosaroxin achieved longer overall survival compared to those treated with placebo (7.5 months versus 6.1 months) and were more likely to achieve complete response or remission to the treatment (30.1% experiencing complete response in the vosaroxin arm versus 16.3% in the placebo arm).

Significantly, patients age 60 or older and those experiencing early relapse experienced the greatest overall survival benefit from the treatment. Early mortality was similar in the two arms, and the most common adverse events were neutropenia or low white blood cell levels, sepsis, and infections as well as mouth sores.

Provided by University of Texas M. D. Anderson Cancer Center

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