

High response rates seen in phase-III trial of chemotherapy, new drug and stem cells in myeloma

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The first study of its kind comparing two different approaches to treating newly diagnosed multiple myeloma has found that both treatments achieved a positive response, researchers said at the 35th Congress of the European Society for Medical Oncology (ESMO) in Milan, Italy.

Dr Antonio Palumbo from Azienda Ospedaliera Universitaria San Giovanni Battista of Torino in Italy and colleagues tested the two approaches for using the drug in a Phase-III trial of 402 patients with newly diagnosed multiple myeloma.

All patients were first administered an induction regimen of the new drug <u>lenalidomide</u> with low-dose dexamethasone. Next they were randomly assigned to one of two consolidation treatments.

The first group of 202 patients received conventional treatment with a combination of melphalan and prednisone, plus lenalidomide. The second group of 200 were given high-dose melphalan plus autologous transplants of their own <u>stem cells</u>.

After the induction treatment, 83% of patients saw a partial response, meaning the level of paraprotein in their blood had dropped by half. Very good partial response (90% reduction in paraprotein) was seen in 34% of patients, and 6% saw a complete response, meaning there was no



detectable paraprotein in their blood.

After the consolidation treatment with melphalan, <u>prednisone</u> and lenalidomide, the very good partial response rate was 56%, and the complete response rate was 14%. After high-dose melphalan plus stem cell transplant, very good partial responses were seen 52% of patients, and complete responses in 25%.

"We are actually pleased with these results, since both treatments improved the quality of response achieved with the induction regimen of lenalidomide and <u>dexamethasone</u>," said Dr Palumbo. "However we need a longer follow-up to assess the impact of this finding on both progression-free survival and overall survival."

"This is the first study that compares high-dose chemotherapy with hemopoietic stem-cell support against conventional-dose chemotherapy plus new drugs, and we are pleased to see that with the actual follow-up there was no difference in response between the two arms of the study."

Commented Professor Martin Dreyling, of Munich University Clinic: "Provided that a longer follow-up confirms the preliminary data on progression-free and overall survival, this ground-breaking study will potentially change the standard of care in younger patients with multiple myeloma. Thus, molecular targeted approaches may finally overcome the current approach based on high-dose chemotherapy and subsequent autologous transplantation."

Provided by European Society for Medical Oncology

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