Darzalex for Multiple Myeloma Can Be Injected Subcutaneously

An advanced study compared intravenous infusions and subcutaneous injections of the antibody treatment.

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People with relapsed or refractory multiple myeloma can receive treatment with subcutaneous injections rather than intravenous (IV) infusions of the antibody treatment Darzalex (daratumumab). A Phase III study comparing the two drug delivery methods found they led to comparable levels of Darzalex in the body and had similar safety profiles. Subcutaneous administration also led to greater patient satisfaction and a lower treatment burden because Darzalex injections could be administered far more quickly than IV infusions.

Maria-Victoria Mateos, MD, PhD, of the University Hospital of Salamanca/IBSAL in Salamanca, Spain, presented findings from the randomized, open-label, noninferiority COLUMBA study at the 2019 American Society of Clinical Oncology annual meeting this week in Chicago. The study sought to compare the efficacy, pharmacokinetics (how the drug is metabolized) and safety of subcutaneous versus IV Darzalex.

The subcutaneous formulation of Darzalex is administered with a drug delivery mechanism known by the brand name Enhanze, or recombinant human hyaluronidase PH20, which allows larger doses to be administered under the skin.

To be eligible for the study, participants needed to have relapsed or refractory (nonresponsive) multiple myeloma and have received at least three prior lines of treatment for the disease, including with a proteasome inhibitor and an immunomodulatory drug. A total of 522 people were evenly randomized to receive subcutaneous injections of 1,800 milligrams of Darzalex (263 people) or IV transfusions of 16 mg of Darzalex per kilogram of body weight .

Those in the IV and subcutaneous groups had respective median ages of 68 years old and 65 years old and respective median body weights of 73 kg and 72.4 kg. A respective 78% and 79% of the study groups were white. A respective 29% and 30% had Stage III multiple myeloma.

The treatment was divided into numbered 28-week cycles. During cycles 1 and 2, all participants received Darzalex once weekly. Then, during cycles 3 through 6, they received the treatment every other week. From cycle 7 onward they received Darzalex every week until their disease

progressed.

In both the IV and subcutaneous groups, 57% of participants stopped the study treatment. The top reasons for discontinuation were progressive disease (44% in the IV group versus 43% in the subcutaneous group), an adverse health event (8% versus 7%), the decision of the participant (2% versus 3%), the decision of the physician (2% versus 4%) and death (1% in both groups).

The members of both study arms were treated for a median of about five months. Whereas it only took about five minutes to administer the subcutaneous injection, the duration of the first IV infusion was a median 7 hours, the second infusion lasted a median 4.3 hours and each subsequent infusion lasted a median 3.4 hours.

The overall response rate to treatment was 37.1% in the IV group and 41.1% in the subcutaneous group, rates that were not statistically significantly different, meaning the difference between them could have been driven by chance. The respective rates of complete response (2.7% versus 1.9%) and very good partial response (17.0% vs. 19.0%) were also comparable.

The maximum lowest concentration of DARA in the body, known as the drug trough, was also similar between the two study groups.

The overall response rate to treatment was comparable across all the study subgroups, including those broken down by body weight. Likewise, the rates of progression-free survival (surviving without the cancer progressing) and overall survival were comparable between the two study groups.

A total of 34.5% of those in the IV group experienced infusion-related reactions, compared with 12.7% who experienced injection-site reactions in the subcutaneous group. This meant that subcutaneous administration reduced the risk of these reactions by 72%. Such reactions were mainly grade 1 or 2; there were no life-threatening grade 4 reactions.

The most common treatment-emergent blood-related adverse events included anemia (low hemoglobin), thrombocytopenia (low platelets), neutropenia (low neutrophils) and lymphopenia (low lymphocytes). The main non-hematologic adverse events included fever, cough, back pain, chills, difficult breathing, diarrhea, nausea, fatigue, upper respiratory tract infections and high blood pressure.

The safety profiles were comparable for the two drug administration methods. A respective 49% and 46% of those in the IV and subcutaneous group experienced a grade 3 or greater treatment-emergent adverse events. A respective 8% and 7% experienced adverse events that led them to discontinue treatment. And a respective 7% and 5% experienced fatal adverse events.

Those who received Darzalex subcutaneously were more satisfied with the cancer treatment than those who received IV administration.

The study authors concluded that subcutaneous Darzalex is noninferior, or comparable to, IV

Darzalex in terms of overall response rates and maximum drug trough after eight weeks of treatment. The study findings support the use of 1,800 mg of Darzalex administered subcutaneously.

To read the conference abstract, click here.

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