Idiotype vaccine therapy (BiovaxID) in follicular lymphoma in first complete remission: Phase III clinical trial results

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Non-Hodgkin's Lymphoma (NHL) is the 6th most common type of cancer in the US. There will be approximately 65,980 new cases diagnosed in the US in 2009.

Follicular Lymphoma (FL) is the 2nd most common type of NHL and accounts for 25% of all NHL. It is a B-cell derived neoplasm, which expresses a specific idiotype marker on the surface of tumor cells. Despite effective chemotherapy regimens, this type of lymphoma typically recurs and becomes resistant to therapy. This study evaluated the use of a vaccine created from the patient's tumor cells.

Participants had been in remission for at least 6 months after standard chemotherapy (though not Rituxan, as this was not yet standard when the study started). A "personalized" vaccine was made for each patient using tissue from lymph node biopsies. Unique markers were identified for each person's lymphoma and, from this, a vaccine that targets this marker was created. The vaccine was then given in conjunction with an immune stimulating agent called GM-CSF, which helps to stimulate an immune response. Normal cells are spared any damage because they do not have the target marker.

One-hundred and seventeen participants received either vaccine (76 patients) or placebo (41 pts). They had stage IIx-IV FL and had achieved at least a 6 month remission after chemotherapy (regimen used was PACE). Participants are still being monitored, but as is common in trials, an interim analysis was done. The median follow up time at this analysis was 56.6 months. The median time to relapse was 44.2 months (vaccine) versus 30.6 (placebo), which was statistically significant (p=0.045). The overall survival has not yet been reached with over 95% of the vaccine and 91% of the placebo arms alive at this follow up. No serious side effects were attributed to the vaccine and the side effects were similar in both groups.

Although similar types of vaccines have been tested previously, this is the first trial to show a statistically significant improvement in progression-free survival in follicular lymphoma patients treated with the vaccine. Previous trials included patients who had partial or complete responses, whereas this trial only vaccinated patients who had no detectable tumor remaining after chemotherapy. Under these conditions, the investigators hypothesized that the vaccine could hold minimal residual disease in check. It is also important to point out that the trial had originally enrolled 234 participants, but 25% did not achieve the 6 month remission. Those patients require further therapy options.
The study is exciting for the field of vaccines, but some new questions arise, including: how does the now standard Rituxan fit into this regimen and is there a better time point to give a vaccine (pre-chemo, in conjunction with chemo).

Also see Interpreting a Cancer Research Study