Alliance Public Study Result Summary
CALGB 50401

What this study is about

A study that compared different drug (chemotherapy) treatments in patients with follicular non-Hodgkin lymphoma.

The full title of this study is: A randomized phase II trial of rituximab versus lenalidomide (REVLIMID™, CC-5013) (IND#73034) versus rituximab + lenalidomide in recurrent follicular non-Hodgkin lymphoma (NHL) that is not rituximab-refractory

Why the study was done

People with follicular non-Hodgkin lymphoma (NHL) have cancer cells in their lymph system, which fights infections and other illnesses. People with NHL usually get treated with either rituximab (common brand name rituxan) or lenalidomide (common brand name revlimid). It was uncommon to use both drugs together before this study was done.

This study was done to see what happened when both drugs were combined instead of using each drug by itself. The study also looked at how long it took for NHL to come back (relapse or recur), how long patients lived after the treatments, and which patients had fewer side effects.

Study results

These results are for people with follicular NHL who had prior treatments before their NHL came back.

The study found that:

- About half of the patients (53%) in Group 2 (lenalidomide only, L) had their NHL respond to treatment.
- About 7 out of every 10 patients (76%) in Group 3 (lenalidomide and rituximab, LR) had their NHL respond to treatment.
- Patients in Group 3 (LR) had more time before their NHL came back
- NHL came back in about 1.1 years in Group 2 (L).
- NHL came back after 2 years in Group 3 (LR).
- Patients in Groups 2 and 3 lived about the same length of time.

Almost 4 out of every 10 patients (36%) in Group 2 were able to finish all of their treatment.
More than 6 out of every 10 patients (63%) in Group 3 were able to finish all of their treatment.
About 2 in every 10 patients (20%) stopped treatment early due to side effects.

About 5 out of every 10 patients had serious side effects in Groups 2 and 3. The most common serious side effects included:

- Patients feeling more tired or fatigued
- Decreased white blood cells, which are important for fighting infections
- Rash
- More patients in Group 3 (LR) had thinner blood, which can cause bleeding.
- More patients in Group 2 (L) had blood clots.

What the results mean

This means that patients with NHL who received LR had a longer response than patient with NHL who got L treatment. Patients in both groups had about the same side effects, and both groups lived about the same length of time.

These results were expected and LR is now a usual treatment for NHL. LR is being studied with other therapies for NHL.

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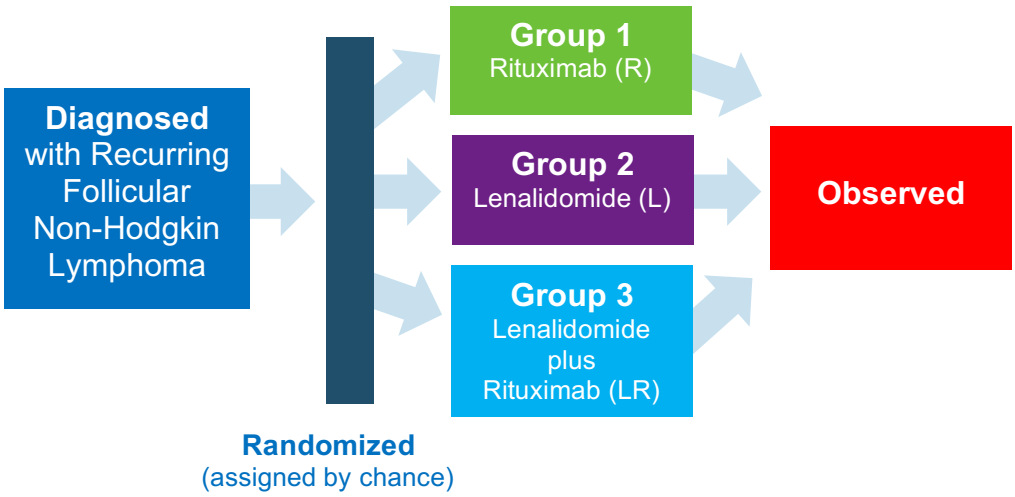
How the study worked

Patients with follicular NHL were assigned by chance (randomized) to one of three groups. This made sure that each patient had the same chance of being in any study group.

- Group 1 got rituximab by vein (IV) in a doctor's office. *This was called R treatment.*
  - The study stopped enrolling patients to Group 1 because doctors did not think it was the best treatment for their patients.
- Group 2 got lenalidomide in a pill. *This was called L treatment.* Patients took lenalidomide by mouth on days 1 through 21 followed by 7 days of rest, every 28 days. These 28 days were called a cycle. Patients could receive up to 12 cycles of treatment if they felt well and their NHL did not get worse.
- Group 3 got both rituximab and lenalidomide. *This was called LR treatment.* Patients took lenalidomide by mouth and also received rituximab by vein on days 8, 15, 22, and 29 – beginning one week after they started taking lenalidomide

Here's a picture that explains how patients were placed into this study.



When did the study start and end? The study started in March 2006. All patients were enrolled by April 2011.

How many patients joined? 97 patients agreed to be in this study. This included 48 that received lenalidomide, 46 that received LR, and 3 that received rituximab.

Talk to your doctor if you want more information about this study.

Scientific publications about this study

This summary includes information in the following article:

- **Randomized Trial of Lenalidomide Alone Versus Lenalidomide Plus Rituximab in Patients with Recurrent Follicular Lymphoma: CALGB 50401 (Alliance).** Leonard JP, Jung SH, Johnson J, Pitcher BN, Bartlett NL, Blum KA, Czuczman M, Giguere JK, Cheson BD. J Clin Oncol. 2015 Nov 1;33(31):3635-40. doi: 10.1200/JCO.2014.59.9258. Epub 2015 Aug 24.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT00238238

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This study was sponsored by the Alliance for Clinical Trials in Oncology – a national clinical trial network group that runs large cancer clinical trials. The Alliance is supported by the National Cancer Institute (NCI) and brings researchers together to develop better treatments for cancers. More information about the Alliance is at http://www.allianceforclinicaltrialsinoncology.org.

This summary lists what is known about this research study as of August 2015.
New Information may be available.

We thank the people who joined this study and made it possible.
We do research to try to learn the best ways to help patients.
The people who joined this study helped us to do that.

Thank you for your interest in learning more about cancer research advances.