Alliance Public Study Result Summary
Study Number A041202

What this study is about

A cancer study that looked at three different treatments in patients who had Chronic Lymphocytic Leukemia (CLL) who were 65 or older.

The full title of this study is: A Randomized Phase III Study of Bendamustine Plus Rituximab Versus Ibrutinib Plus Rituximab Versus Ibrutinib Alone in Untreated Older Patients (≥ 65 Years of Age) with Chronic Lymphocytic Leukemia (CLL)

Why the study was done

This study was done to compare the effects, good and bad, of three different treatments for CLL to see which therapy was the most effective.

The study researchers also wanted to learn more about patients' fatigue and quality of life while getting treatment in order to know how older patients tolerated each treatment.

Study results

These results are for people with Chronic Lymphocytic Leukemia (CLL), who were 65 or older who had never been treated for CLL but whose CLL whose disease has worsened (progressed) to the point where treatment was recommended.

The study found the following:

- Patients had longer time before their disease worsened when treated with ibrutinib compared to patients treated with bendamustine and rituximab
- Patients had longer time before their disease worsened when treated with ibrutinib plus rituximab compared to patients treated with bendamustine and rituximab.
- There was no difference in time before their disease worsened in patients treated with ibrutinib compared to patients treated with ibrutinib and rituximab
- There was no significant difference among the three treatment groups in how many patients were still alive 38 months after treatment.

The results about patients' fatigue and quality of life have not yet been published.

The most common side effects included:

- 61 out of every 100 patients (61%) who took bendamustine plus rituximab had blood-related side effects
- 40 out of every 100 patients (40%) who took ibrutinib alone had blood-related side effects
- 39 out of every 100 patients (39%) who took ibrutinib plus rituximab had blood-related side effects

Blood related side effects included anemia, low white blood cell count and decreased platelet count.

- 63 out of every 100 patients (63%) who took bendamustine plus rituximab had non blood-related side effects
- 74 out of 100 patients (74%) of patients who took either ibrutinib alone or ibrutinib plus rituximab had non blood-related side effects

Non-blood related side effects included infection and high blood pressure.

What the results mean

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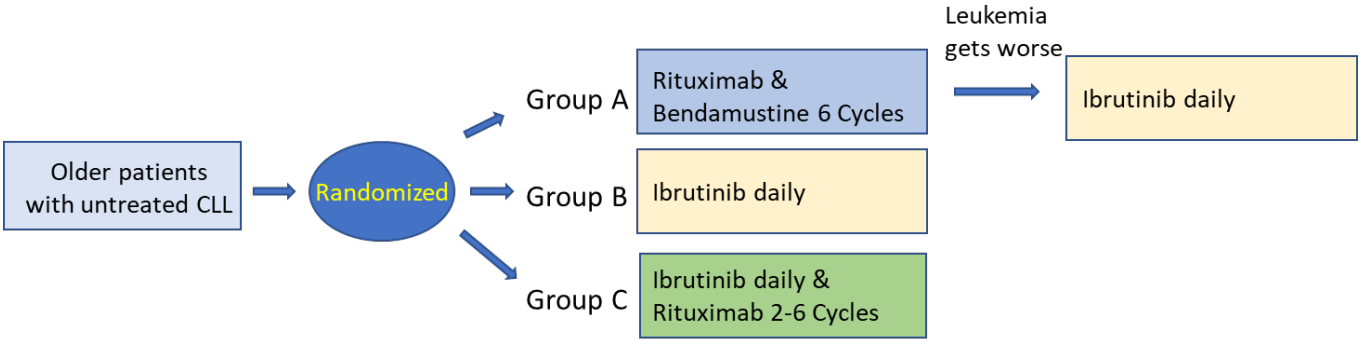
For older patients with untreated CLL those treated with ibrutinib alone had longer time before their disease worsened when compared to those treated with bendamustine plus rituximab, meaning that ibrutinib was more effective.

For older patients with untreated CLL those treated with ibrutinib plus rituximab had longer time before their disease worsened when compared to those treated with bendamustine plus rituximab, meaning that ibrutinib plus rituximab was more effective.

There was no difference in time when disease worsened between patients treated with ibrutinib alone and patients treated with ibrutinib and rituximab.

How the study worked

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



Randomization is the process by which patients are assigned by equal chance into one of the separate groups.
Rituximab is given in your vein for 1 day every cycle (28 days) for 6 cycles for Group A and 1 day every cycle (28 days) for cycles 2 through 6 for Group C.
Bendamustine is given in your vein for 2 days every cycle (28 days) for 6 cycles

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Ibrutinib is a capsule taken by mouth every day (3 capsules total each day given at once) until leukemia gets worse.

Patients 65 years of age or older with untreated CLL were randomly assigned to receive bendamustine plus rituximab (Group A), ibrutinib (Group B), or ibrutinib plus rituximab (Group C). Patients were followed until their leukemia got worse. Patients in Group A could receive ibrutinib if their leukemia got worse after receiving bendamustine plus rituximab.

When did the study start and end?
The study started in December 2013. All patients were enrolled by May 2016.

How many patients joined?
547 patients were enrolled at 219 sites throughout the United States and Canada

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

Scientific publications about this study

Details about the study can be found in these articles:

- Woyach JA, Ruppert AS, Heerema NA, Zhao W, Booth AM, Ding W, Bartlett NL, Brander DM, Barr PM, Rogers KA, Parikh SA, Coutre S, Hurria A, Brown JR, Lozanski G, Blachly JS, Ozer HG, Major-Elechi B, Fruth B, Nattam S, Larson RA, Erba H, Litzow M, Owen C, Kuzma C, Abramson JS, Little RF, Smith SE, Stone RM, Mandrekar SJ, Byrd JC. Ibrutinib Regimens versus Chemoimmunotherapy in Older Patients with Untreated CLL. N Engl J Med. 2018 Dec 27;379(26):2517-2528. doi: 10.1056/NEJMoa1812836. Epub 2018 Dec 1. PMID: 30501481; PMCID: PMC6325637.

To learn about this trial, visit the ClinicalTrials.gov website at
https://clinicaltrials.gov/ct2/show/NCT01886872

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 www.AllianceNCTN.org.

This summary lists what is known about this research study as of November 2020.

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.