# Alliance Public Study Result Summary in Follicular Lymphoma Study Number C50904

## What this study is about

A cancer study that looked at whether adding bortezomib to ofatumumab + bendamustine in patients with untreated follicular lymphoma lived longer and/or lived more time before the disease worsened.

The full title of this study is: A Randomized Phase II Trial of Ofatumumab and Bendamustine vs. Ofatumumab, Bortezomib (NSC # 681239) and Bendamustine in Patients With Untreated Follicular Lymphoma

## Why the study was done

This study was done to see if adding bortezomib to ofatumumab + bendamustine in the treatment of patients who have not had previous treatment for Follicular Lymphoma resulted in those patients living longer and/or living more time before the disease worsens.

## Study results

These results are for people with follicular lymphoma that had not had previous treatment.

The study found that adding bortezomib to ofatumumab and bendamustine did not help patients live longer or live more time before their disease worsened.

The most common serious side effects included:

**ARM A:**
Overall blood related side effects were experienced in 68 out of every 100 patients (68%)

Which includes:

- 52 out of every 100 patients (52%) had lymphopenia (decreased white blood cells)
- 36 out of every 100 patients (36%) had neutropenia (low number of immune system cells that kill bacteria)
- 5 out of every 100 patients (5%) had fatigue (feeling tired)
- 5 out of every 100 patients (5%) had diarrhea (loose watery poop)

**ARM B:**
Overall blood related side effects were experienced in 66 out of every 100 patients (66%)

Which includes:

- 55 out of every 100 patients (55%) had lymphopenia (decreased white blood cells)
- 31 out of every 100 patients (31%) had neutropenia (low number of immune system cells that kill bacteria)
- 13 out of every 100 patients (13%) had fatigue (feeling tired)
- 11 out of every 100 patients (11%) had diarrhea (loose watery poop)

- 8 out of every 100 patients (8%) had nausea* (feeling sick to your stomach)
- 8 out of every 100 patients (8%) had vomiting **(being sick to your stomach, throwing up)

*nausea was only reported in Arm B patients
**vomiting was only reported in Arm B patients

## What the results mean

This means patients in Arm B appeared not to benefit from adding bortezomib to their treatment. It is not recommended that bortezomib be added to the first round of treatment in follicular lymphoma. Adding bortezomib did not resulted in patients living longer and/or living more time before the disease worsens.

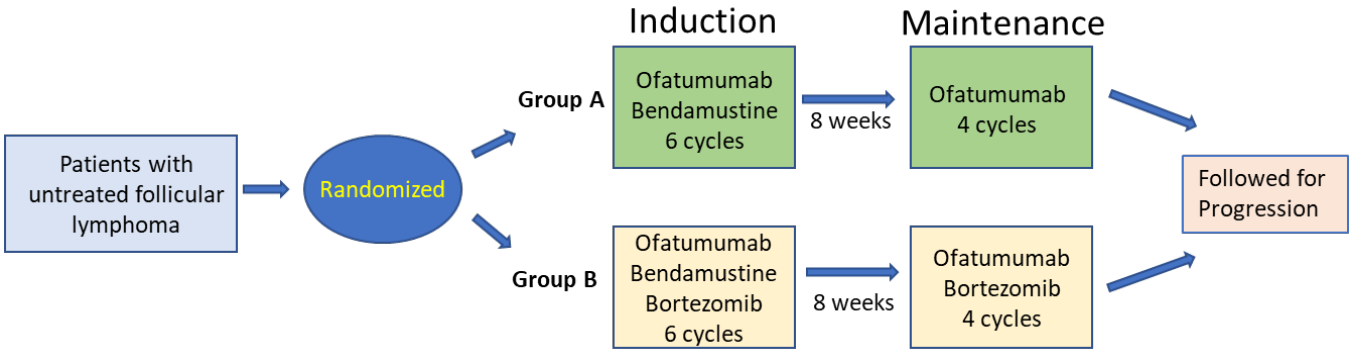
Side effects were worse when bortezomib was added to treatment leading to severe fatigue, vomiting and neuropathy. The severe side effects led to more patients requiring lowering of treatment doses and fewer patients were able to complete the planned treatment and maintenance cycles.

These results were unexpected, but it was anticipated, that a longer follow-up of patients would provide more insight into the survival of high-risk patients.

## How the study worked

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

After registration patients were randomized by a computer to Arm A or Arm B




**Randomization** is the process by which patients are assigned by chance to separate groups.

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**Treatment Phase**

**1 Cycle** is 35 days
**Ofatumumab** 300 mg was given IV on day 1 of cycle 1 and 1000 mg was given on day 1 of cycles 2-6, immediately prior to bendamustine
**Bendamustine** 90 mg/mm$^2$ given IV over 30-60 minutes on days 1 and 2 of each cycle
**Bortezomib** 1.6 mg/mm$^2$ (IV or SC) on days 1, 8, 15, and 22 of each cycle

**Maintenance Phase**

**1 Cycle** is 56 days during maintenance.
**Ofatumumab** 1000 mg given IV on day 1 of each cycle
**Bortezomib** 1.6 mg/mm$^2$ (IV or SC) on days 1, 8, 15, and 22 of each cycle.

**When did the study start and end?** The study started in April 2011. All patients were enrolled by the end of April 2016.

**How many patients joined?** 135 patients agreed to be in this study. Only 128 patients completed the study. 66 patients joined Arm A and 62 patients joined Arm B.

**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:


- Blum KA, Polley MY, Jung SH, Dockter TJ, Anderson S, Hsi ED, Wagner-Johnston N, Christian B, Atkins J, Cheson BD, Leonard JP, Bartlett NL. Randomized trial of ofatumumab and bendamustine versus ofatumumab, bendamustine, and bortezomib in previously untreated patients with high-risk follicular lymphoma: CALGB 50904 (Alliance). Cancer. 2019 Oct 1;125(19):3378-3389. doi: 10.1002/cncr.32289. Epub 2019 Jun 7. PMID: 31174236; PMCID: PMC6744328.


To learn about this trial, visit the ClinicalTrials.gov website at https://clinicaltrials.gov/ct2/show/NCT01286272

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 July 2021.*

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***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.*