

The safety and efficacy of bosutinib in Japanese adults with newly diagnosed chronic myeloid leukemia

Date of summary: December 2019

Study number: NCT03128411 | Study start date: May 2017 | Estimated study end date: November 2020

The full title of this abstract is: Phase 2 Study of Bosutinib in Japanese Patients With Newly Diagnosed Chronic Phase Chronic Myeloid Leukemia

This study drug is not approved to treat the condition under study in Japan, the country where the clinical trial that is discussed in this summary was conducted.









Researchers must look at the results of many types of studies to understand whether a study drug works, how it works, and whether it is safe to prescribe to patients.

This summary reports the results of only one study. The results of this study might be different from the results of other studies that the researchers look at.

This summary reports the interim results from the study – results may not be the same when the study is complete.

More information can be found in the scientific abstract of this study, which you can access here: [View ASH Abstract](#)

Click to find out how to say tricky medical terms ^

-  **Bosutinib** <boh-SOO-tih-nib> 
-  **Leukemia** <loo-KEE-mee-ah> 
-  **Myeloid** <MY-eh-loyd> 
-  **Neutrophil** <NOO-troh-fil> 

What did this study look at?

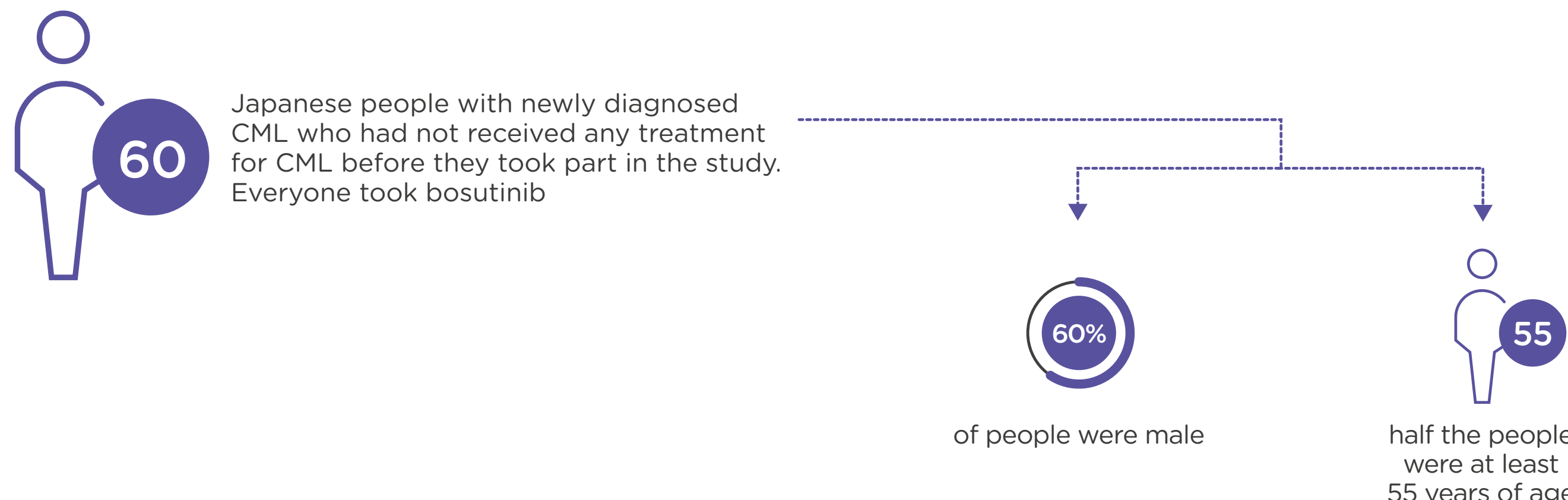
- Chronic myeloid leukemia (CML for short) is a type of cancer that affects white blood cells. It tends to progress slowly over many years.
 - CML is caused by an alteration in a gene called BCR-ABL, which causes the cancer cells to increase in number.
 - Genes are segments of DNA* and are found in structures called chromosomes within each cell of the body. BCR-ABL is found in a chromosomes called the Philadelphia chromosome, which is present in some types of leukemia cancer cells.
- Bosutinib is a type of medicine known as a tyrosine kinase inhibitor.
 - Tyrosine kinases are proteins in the body that control how cells grow and divide.
 - Bosutinib works by blocking tyrosine kinase in the cancer cells, causing them to die.
- In many countries, including Japan, bosutinib is an approved treatment for people with CML whose

cancer is no longer responding to treatment with other tyrosine kinase inhibitors (such as imatinib, dasatinib, and nilotinib), or who have stopped their previous treatment because they could not tolerate it.

- In this study, researchers investigated bosutinib as a treatment for Japanese people over the age of 18 with newly diagnosed CML.
- Researchers measured the level of BCR-ABL protein to see how well bosutinib works and looked at any medical problems** that people developed.
- This summary describes the safety and efficacy*** of bosutinib in this group of people.

* DNA contains genetic information that regulates activity inside a cell.
 ** Medical problems could be caused by reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could have been caused by a study treatment, or by another medicine the participant was taking.
 *** Efficacy is how well a drug works within a clinical trial.

Who took part in this study?

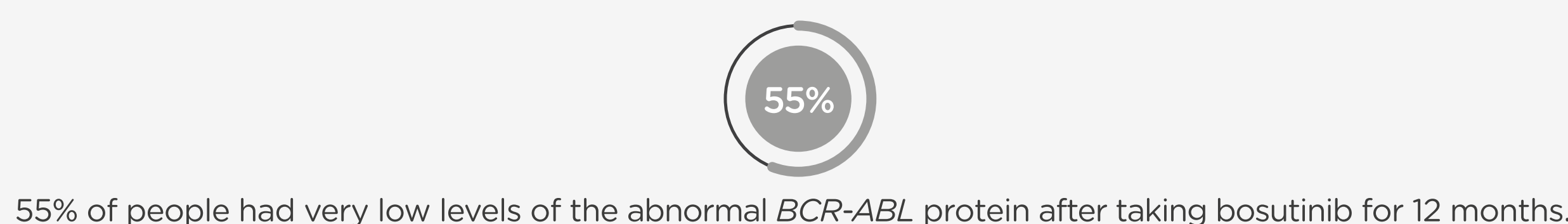


What were the results of the study?

- Half of the people took bosutinib for around 15 months. Half of the people were followed for around 17 months.

Efficacy

The researchers measured the levels of the abnormal BCR-ABL protein in people to see how effective the treatment was.



Safety

The proportion of people on treatment after 12 months of taking bosutinib



The proportion of people experiencing the most common medical problems were:



The proportion of people experiencing the most common severe**** medical problems were:



- The researchers also looked at the levels of bosutinib in the blood. They found that the lowest level of bosutinib was slightly higher in Japanese people compared with other studies in people from different countries.

**** A medical problem is considered "severe" when it limits daily activities such as bathing and dressing, is disabling or is medically significant, or could be life-threatening, need hospital care, or cause lasting problems.

More results from this study can be found here: [View ASH Abstract](#)

What were the main conclusions reported by the researchers?

- A similar proportion of Japanese people in this study had low levels of the abnormal BCR-ABL protein after 12 months of taking bosutinib treatment compared with people in other studies in different countries.
- To date, researchers have not identified any new medical problems in this study in light of what they already know about the medicine from previous studies.
- These results suggest that bosutinib is an effective treatment option for Japanese people with newly diagnosed CML.

Who sponsored this study?

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Pfizer would like to thank all of the people who took part in this study.

Further information

Click to show more information on the study and clinical trials in general ^

For more information on this study, please visit:

[View ASH Abstract](#)
<https://clinicaltrials.gov/ct2/show/NCT03128411>

For more information on clinical studies in general, please visit:

<https://www.clinicaltrials.gov/ct2/about-studies/learn>
<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are>