

# Does the benefit of living longer outweigh the risk of developing medical problems for people with AML treated with glasdegib?

Date of summary: December 2019

Study number: NCT01546038 | Study start date: June 2012 | Study end date: March 2019

The full title of this abstract is: Quality-Adjusted Survival for Low-Dose Cytarabine (LDAC) versus Glasdegib+LDAC among Newly Diagnosed Acute Myeloid Leukemia Patients who are not Candidates for Intensive Chemotherapy: A Q-TWiST Analysis

Glasdegib is approved in the United States to treat the condition discussed in this summary. Cytarabine is approved to treat the condition discussed in this summary.

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.

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 ^

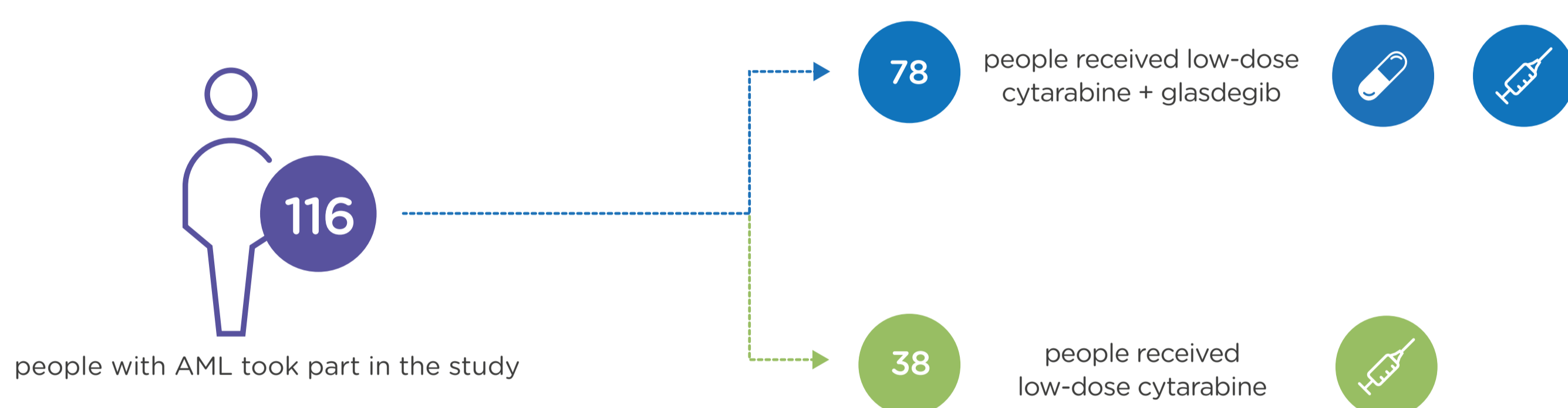
- Cytarabine <sy-TAYR-uh-been>
- Glasdegib <glas-DEH-gib>
- Myeloid leukemia MY-eh-loyd loo-KEE-mee-uh>

## What did this study look at?

- Acute myeloid leukemia (AML for short) is a type of blood cancer.
  - In AML, the body produces too many of a certain type of white blood cell that doesn't develop properly. Acute means that the cancer grows quickly.
- Intensive chemotherapy is often the first treatment used for AML. The aim is to destroy as many leukemia cells as possible.
  - However, this can mean that people spend a long time in hospital and they may develop medical problems\*. This can have a negative impact on their quality of life.
- Some people with AML cannot receive intensive chemotherapy, for example because they are older or have certain health conditions. Instead, these people may receive less intensive chemotherapy, such as low-dose cytarabine.
- Glasdegib is approved in the United States to treat AML in people older than 75 years who cannot receive intensive chemotherapy.
  - Glasdegib reduces the activity of a network of connected proteins (called the 'hedgehog' pathway) that helps control how cells in the body develop and multiply.
  - Overactivity of this pathway can boost the growth of some cancers.
- A previous study showed that people with AML who received low-dose cytarabine + glasdegib lived longer than those who received only low-dose cytarabine.
- In this analysis, researchers used a mathematical model to compare how long people lived with different levels of health.
- They looked at how long people with AML receiving either low-dose cytarabine + glasdegib or only low-dose cytarabine lived:
  - with severe medical problems\*\*
  - after stopping treatment due to their cancer getting worse (known as progression), or
  - without developing severe medical problems or their cancer progressing
- This summary describes whether the benefits of living longer outweighed the risks of developing medical problems or their cancer getting worse for people treated with glasdegib.

\* 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.  
 \*\* 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.

## Who took part in this study?



## What were the results of the study?

### How long people with AML lived

After 20 months

28 in 100 people who received low-dose cytarabine + glasdegib were still alive

8 in 100 people who received low-dose cytarabine were still alive

If left untreated, AML progresses quickly and can lead to death within weeks

### Medical problems and AML progression

People who received low-dose cytarabine + glasdegib

- lived around 3 months longer without their cancer getting worse or developing severe medical problems than people receiving low-dose cytarabine
- had severe medical problems for around 1 month longer than people receiving low-dose cytarabine
- There was only a small difference between the two groups in how long people lived after stopping treatment for AML

### How long people lived after taking quality of life into account

People receiving low-dose cytarabine + glasdegib lived around 4 more months with a better quality of life than people receiving only low-dose cytarabine

Researchers estimated this was a 75% improvement in the time people lived without medical problems due to AML treatment or their cancer progressing

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

## What were the main conclusions reported by the researchers?

- In this analysis, people who received low-dose cytarabine + glasdegib lived longer, remained on treatment longer, and had severe medical problems for longer than people who received only low-dose cytarabine. However, they lived longer with a better quality of life than people receiving only low-dose cytarabine.
  - This suggests that the benefits of living longer with a better quality of life can outweigh the risk of developing medical problems for people treated with low-dose cytarabine + glasdegib.

## 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://www.clinicaltrials.gov/ct2/show/NCT01546038](https://www.clinicaltrials.gov/ct2/show/NCT01546038)

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>