

Effects of glasdegib plus chemotherapy in people with acute myeloid leukemia

Date of summary: December 2019 Study number 1: NCT02367456 | Study start date: April 2015 | Estimated study end date: January 2021

Study number 2: NCT01546038 | Study start date: June 2012 | Study end date: March 2019

The full title of this abstract is: Clinical Benefit of Glasdegib in Combination with Azacitidine or Low-dose Cytarabine in Patients with Acute Myeloid Leukemia

approved to treat the condition under study that is discussed in this summary.

Glasdegib combined with low-dose cytarabine is

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 two studies.

The results of these studies might be different from the results of other studies that the researchers look at.

study is complete. More information can be found in the scientific abstract of this summary, which you can access here:

This summary reports the interim results from

Study 1 - results may not be the same when the

View ASH Abstract



quickly.

develop properly.

blood cells.

normal blood cells.

intensive chemotherapy.

Study 1

Azacitidine <ay-zuh-SY-tih-deen>

Click to find out how to say tricky medical terms A

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

What did this summary look at?

Acute myeloid leukemia (AML for short) is a type of

blood cancer. Acute means that the cancer grows

certain type of white blood cell that doesn't

Intensive chemotherapy is often the first treatment

- This can prevent the body from producing normal

used for AML because it provides the best chance of

controlling the cancer. The aim is to destroy as many

leukemia cells as possible and restore production of

- Doctors consider people's age and health when

- Intensive chemotherapy may not be a good choice

problems. For these people, the risk of developing

medical problems may outweigh the benefits of

deciding what type of chemotherapy to use.

for older people or people with other health

- These people may receive less intensive

- In AML, the body produces too many of a

States for people with AML who meet three specific criteria: - They have not received previous treatment for their AML.

Glasdegib is an approved treatment in the United

- They are 75 years of age or older, or have other health problems that prevent them from taking intensive chemotherapy.
- They must be taking glasdegib in combination with low-dose cytarabine. Glasdegib reduces the activity of a network of
 - control how cells in the body develop and multiply. - Overactivity of the hedgehog pathway can boost

the growth of some cancers.

proteins (called the 'hedgehog' pathway) that helps

- In these studies, researchers looked at people with AML who took glasdegib with other chemotherapies. They wanted to see whether the risk of developing medical problems was balanced by the benefits of treatment.
- treatment? 2. Did treatment provide any benefits in controlling AML?

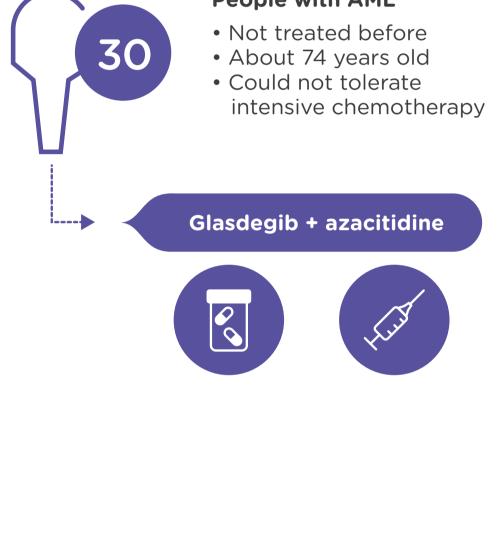
This summary looks at the following questions:

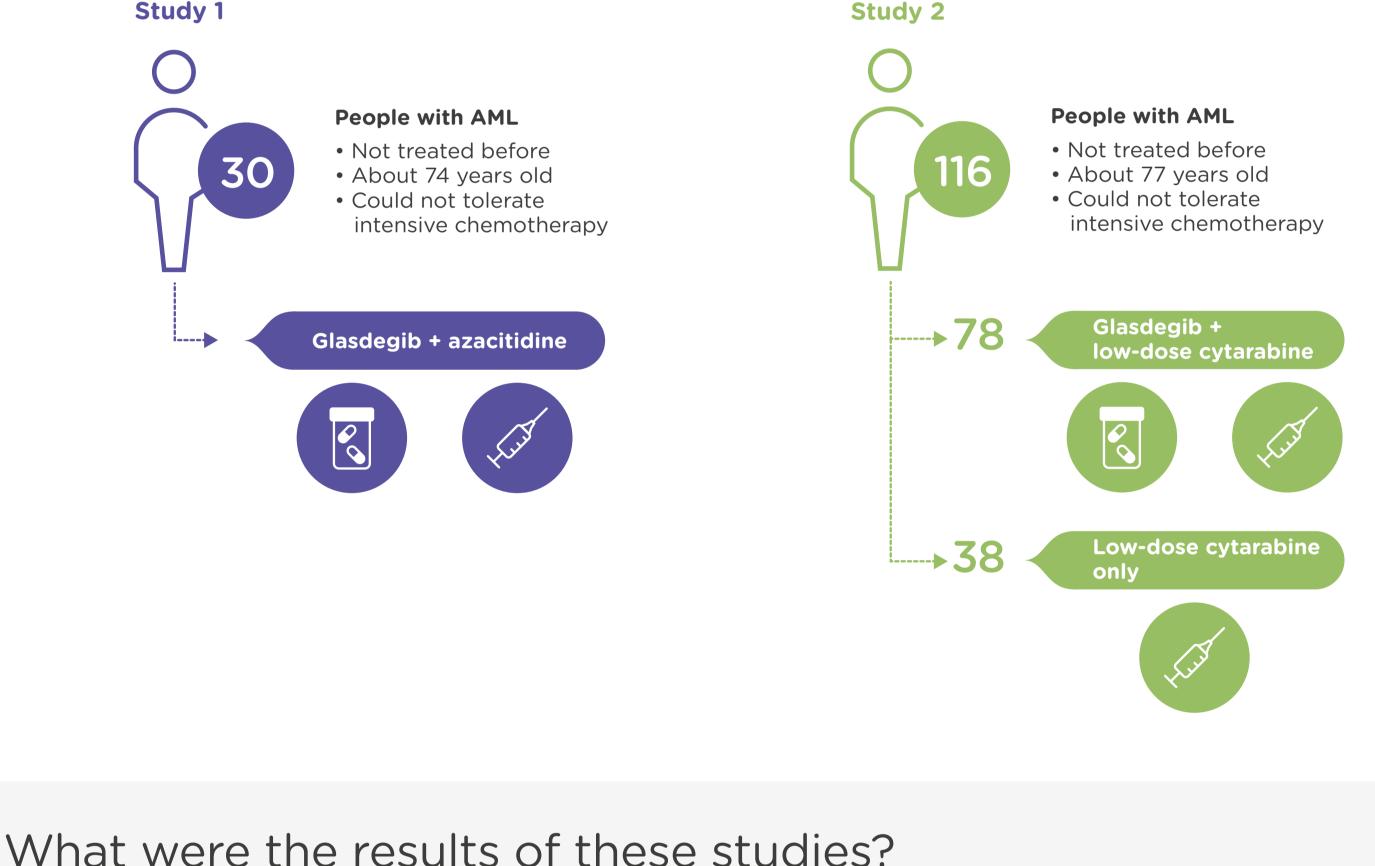
1. How often did medical problems occur with

- chemotherapies, such as azacitidine or low-dose cytarabine. These may be less likely to cause serious medical problems. Some cancer therapies are combined with azacitidine
- or low-dose cytarabine because the combination may work better. People who have medical problems with combination therapy may need to pause treatment until the problems get better.

People with AML

Who took part in these studies?





Study 1

Glasdegib

Study 2

Glasdegib

+ low-dose

cvtarabine

60%

Low-dose

Glasdegib

Study 1 Study 2

Glasdegib

Glasdegib



What were some of the medical problems people had during treatment?

Low-dose

Did treatment provide any benefits in controlling AML? People whose cancer was

cytarabine alone.

Glasdegib +

azacitidine

glasdegib combination treatment than with low-dose cytarabine alone.

People living 6 months after completely controlled treatment started

- Serious medical problems, such as infections, occurred with glasdegib combination treatment and low-dose

Study 1 Study 2 Study 2 Study 1

Glasdegib

+ low-dose

cytarabine



• In older people and people with other health problems who cannot receive intensive chemotherapy for AML, the risk of medical problems and benefits of glasdegib combination treatment appeared to be well balanced.

in this study.

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Who sponsored these studies?

Phone (United States): +1 212-733-2323

Pfizer would like to thank all of the people who took part

Glasdegib +

azacitidine

Further information

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

For more information on this study, please visit:

View ASH Abstract Study number 1: https://clinicaltrials.gov/ct2/show/NCT02367456

Study number 2: https://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

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