What this study is about

This cancer study measured how age affects the time it takes for the drug busulfan to leave patients' bodies when it is given as part of a stem cell transplant.

The full title of this study is: Effect of age on the pharmacokinetics of busulfan in patients undergoing hematopoietic cell transplantation: An Alliance study (CALGB 10503, 19808, and 100103)

Why the study was done

Older patients with cancers called acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS) are often left out of treatments that include a drug called busulfan (also called Myleran® or Busulfex IV®). This happens because older people often have other illnesses that could cause more side effects or death. Researchers thought older patients might not be able to clear busulfan from their bodies quickly, which might lead to more side-effects.

Study results

These results are for people who are at least 18 years old and have acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS).

The study found that:

- Patients in Group A (60+ years) cleared more busulfan from their bodies than Group B.

This result was not expected.

What the results mean

This means that the amount of busulfan that leaves the body does not explain the reasons some older patients have more side effects from busulfan. Future studies that use busulfan should enroll all age groups and include a plan to measure many factors to explain why some older patients have more side effects.

How the study worked

This study was done to see how busulfan leaves the body in older patients (>60 years), compared to younger patients.

Researchers reviewed the results of three past studies that treated patients with AML and MDS. These patients received busulfan before getting a transplant called hematopoietic (blood) cell transplantation (also called a stem cell or bone marrow transplant).

Blood was drawn from patients after their first busulfan treatment. Levels of busulfan were measured and compared by age group.

Patients were placed into two age groups:

- Group A had patients who were at least 60 years old
- Group B had patients under 60 years old

When did the study start and end? The studies started in 2004. All patients were enrolled by the end of 2011.

How many patients joined? 174 patients were in this study. 29 were at least 60 years old.

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:

- **Effect of age on the pharmacokinetics of busulfan in patients undergoing hematopoietic cell transplantation; an alliance study (CALGB 10503, 19808, and 100103).**
  Beumer JH, Owzar K, Lewis LD, Jiang C, Holleran JL, Christner SM, Blum W, Devine S, Kolitz JE, Linker C, Vij R, Alyea EP, Larson RA, Ratain MJ, Egorin MJ
  Cancer Chemother Pharmacol. 2014 Nov;74(5):927-938. Epub 2014 Aug 28.
- **Maintenance Therapy with Decitabine in Younger Adults with Acute Myeloid Leukemia (AML) in First Remission: A Phase II Cancer and Leukemia Group B Study (CALGB 10503, Alliance)**
  Blum W, Sanford B, Klisovic RB, Deangelo DJ, Uy G, Powell BL, Stock W, Baer MR, Kolitz JE, Wetzler M, Hoke E, Bloomfield CD, Geyer S, Marcucci G, Stone RM, Larson RA
  Blood vol 120 (21) -44

This study was sponsored by the Cancer and Leukemia Group B, which is part of the Alliance for Clinical Trials in Oncology – a national cooperative network 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 http://www.allianceforclinicaltrialsinoncology.org.

This summary lists what is known about this research study as of October 2014. New Information may be available.

We thank the people who joined this study and made it possible. *This study could have been completed faster if more people who had the opportunity to participate would have done so. If you know people who are offered the chance to join a cancer clinical trial, please encourage them to enroll. 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. We appreciate your advocating for federally-funded research to your elected representatives.