

NCT# 02458235

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO (UCSF)

**ASSENT TO BE IN A RESEARCH STUDY
ABOUT CANCER TREATMENT**

For RECIPIENT children 7-12 years old

A phase II study of donor lymphocyte infusion in combination with azacitidine for the prevention of hematologic malignancy relapse following allogeneic stem cell transplantation

Name of recipient _____

Why are we meeting with you?

We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something. [REDACTED] and some other doctors are doing a study to learn more about children with cancer. After we tell you about it, we will ask if you'd like to be in this study or not.

Why are we doing this study?

The study is being done to learn more about treatments done after blood or bone marrow transplants to help get rid of your own cells in the blood after the transplant. The study doctors hope this treatment will make it less likely that your cancer will return.

What will happen to you if you are in the study?

Only if you agree, these things will happen:

1. After your transplant, once your white blood cells build up again (usually 4-5 weeks), your doctor will check whether you have any signs of a sickness called graft-versus-host disease (GVHD). GVHD happens when your donor's cells attack your own cells after the transplant, which can cause problems like skin rash, diarrhea, yellow skin or yellow eyes. We will also test your blood and bone marrow for donor's cells. The doctors will do both these things even if you are not in this study. The next parts of your treatment will depend on two things: 1) whether you have graft-versus-host disease, 2) whether your bone marrow has mostly your cells or mostly your donor's cells, and 3) whether there are any cancer cells still in your blood
2. If you do not have graft-versus-host disease, then the treatments which help your body accept your donor's cells will be slowly stopped. If there are mostly donor cells in your bone marrow, these treatments will be stopped over 10 weeks, and you will start taking a drug called azacitidine once they are over. Every 6 weeks you will take azacitidine for

up to 4 days in a row for up to 7 separate times (called cycles). Azacitidine can be given through your veins in the clinic or at home as a shot under your skin.

3. If there is a mixture of your own cells and your donor's cells, then the treatments which help your body accept your donor's cells will be stopped over 4 weeks instead of 10. You will then take azacitidine in the same way as the group above. You may also receive more cells from your donor, called donor lymphocyte infusions on day 5 of each cycle if there are enough donor cells. These cells will be given directly into your veins. Each time you are given more donor cells, the amount of these cells will increase if you are not having too many problems from this treatment.
4. You will be watched for signs of graft-versus-host disease (GVHD) regardless of which treatment you are receiving. You will be asked to call your doctor right away if a rash, diarrhea or jaundice appears. If you develop signs of graft-versus-host disease, your doctor will start treating that disease by giving you more medicine. You will be asked to come back to the clinic more often (maybe as often as once a week) and you may even need to spend a night in the hospital. The doctors will do these things even if you are not in this study.
5. It is possible that the number of donor cells in your blood will change during your treatment. Because of this, your doctor will test your blood 4-8 weeks after each cycle of azacitidine and check your bone marrow every two cycles.
6. If your bone marrow tests show a small number of cancer cells in the bone marrow (less than 1 in 100 cells) you will continue with treatments on this study. If the amount of cancer cells is large, you may stop the study treatment and get other treatments recommended by your doctor.

Will this study hurt?

Drawing blood through the central line (the tube that is used to give you medicine and blood) does not hurt. Bone marrow are the cells inside of your bone and you will be given anesthesia (medicine to make you sleep) so you will not feel the bone marrow being taken out. If you get a skin rash, it may be itchy. Diarrhea can cause some stomach pain. Yellowing of the skin and eyes usually does not hurt. If you get a skin rash and diarrhea, you will probably be admitted to the hospital to get pain medicine and other medicine to treat your symptoms.

Will you get better if you are in this study?

The treatment in this study may help keep your sickness from coming back in the future, but there is also a chance that it will not help. The doctors might find out something that will help other children like you later.

Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

Do you have to be in the study?

No, you don't. No one will be mad at you if you don't want to do this. If you don't want to be in this study, just tell us. Or if you do want to be in the study, tell us that. And, remember, you can say yes now and change your mind later. It's up to you.

If you don't want to be in this study, just tell us.

If you want to be in this study, just tell us.
The doctor will give you a copy of this form to keep.

SIGNATURE OF PERSON CONDUCTING ASSENT DISCUSSION

I have explained the study to _____ (*print name of child here*) in language he/she can understand, and the child has agreed to be in the study.

Signature of Person Conducting Assent Discussion

Date

Name of Person Conducting Assent Discussion (*print*)

Signature of Translator, if applicable

Date