

Informed Consent Coversheet

Official Study Title:	CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT
NCT number:	NCT02050347
Date of Consent:	02/08/23

CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT FORM

HIPAA Compliant

H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

Background

In this consent form, "you" means you or your child.

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study. Taking part in this study is voluntary.

You have a type of lymph gland cancer called non-Hodgkin lymphoma, acute lymphocytic leukemia or chronic lymphocytic leukemia (throughout the rest of this consent these diseases will be referred to as "lymphoma" or "leukemia"). Your lymphoma or leukemia has come back or has not gone away after treatment (including the best treatment we know for these cancers). Because there is no standard treatment for your cancer at this time, you are being asked to volunteer to be in a gene transfer research study using special immune cells. You may have already thought a lot about being in this study. You may even have already made a decision about whether to be in the study. Even if this is true for you, it is important that we give you this information and talk about it before we start you in the study.

The body has different ways of fighting infection and disease. No one way seems perfect for fighting cancers. This research study combines two different ways of fighting disease, antibodies and T cells, hoping that they will work together. Antibodies are types of proteins that protect the body from bacterial and other diseases. T cells, also called T lymphocytes, are special infection-fighting blood cells that can kill other cells including tumor cells. Both antibodies and T cells have been used to treat patients with cancers; they have shown promise, but have not been strong enough to cure most patients.

T lymphocytes can kill tumor cells but there normally are not enough of them to kill all the tumor cells. Some researchers have taken T cells from a person's blood, grown more of them in the laboratory and then given them back to the person.

The antibody used in this study is called anti-CD19. It first came from mice that have developed immunity to human lymphoma. This antibody sticks to cancer cells because of a substance on the outside of these cells called CD19. CD19 antibodies have been used to treat people with lymphoma and leukemia. For this study, the CD19 antibody has been changed so that instead of floating free in the blood it is now joined to the T cells. When an antibody is joined to a T cell in this way it is called a chimeric receptor. The T lymphocytes will also contain CD28, which stimulates T cells and makes them last longer.

Treatment with CD19/CD28 chimeric receptor-T cells has had activity against lymphoma and leukemia when the cells are made from the patients affected by these diseases. In this study we are going to see if this treatment works even better when we make these cells from a healthy stem cell donor. If we were not able to collect blood from your stem cell donor (if they were not available to donate or if they chose not to donate more), we collected blood from you to make the CD19/CD28 chimeric receptor-T cells. In that case, we collected the blood after your stem cell transplant had engrafted (taken) so that most or all of the T cells in your blood would actually be coming from your donor.

Patient Name/ID #: _____
Protocol Version 8.2

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Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT FORM

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H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

If we are successful, we hope that these new cells may be able to work better and target and kill lymphoma and leukemia cells. However, we do not know that yet. These CD19/CD28 chimeric receptor T cells are investigational products not approved by the Food and Drug Administration.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of this study is to find the biggest dose of chimeric T Cells that is safe, to see how long T cells with this chimeric receptor last, to learn what the side effects are, and to see whether this therapy might help people with lymphoma or leukemia after a stem cell transplantation from a donor.

Procedures

The research will be conducted at the following location(s):

Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

Up to 40 subjects may be treated on this study.

Earlier, you or your donor gave us blood to make CD19/CD28 chimeric receptor-T cells in the laboratory. These cells were grown and frozen for you. To make the T cells, we took your donor's blood (or your blood) and stimulated it with growth factors to make the T cells grow. To get the CD19 antibody with CD28 to attach to the surface of the T cell, we inserted the antibody gene into the T cell. This is done with a virus called a retrovirus that has been made for this study and will carry the antibody gene into the T cell. This virus also helps us find the T cells in your blood after we inject them using a special laboratory test. Because you have received cells with a new gene in them, you will be followed for a total of 15 years to see if there are any long term side effects of gene transfer. If you cannot visit the clinic, you may be contacted by the research coordinator or physician.

When you enroll on this study, you will be assigned a dose of CD19/CD28 chimeric receptor-T cells. You should not receive other cancer treatment until 6 weeks after your cell infusion.

You will be given an injection of cells into the vein through an IV at the assigned dose. Before you receive the injection, you may be given a dose of Benadryl (Diphenhydramine) and Tylenol (Acetaminophen). The injection will take up to 10 minutes. We will follow you in the clinic after the injection for up to 4 hours. If after a 4-6 week evaluation period after your infusion, you seem to be experiencing a benefit (confirmed by radiological studies, physical exam and/or symptoms), you may be able to receive up to 5 additional doses of the T cells if you wish. These additional infusions would be at least 4-6 weeks apart and at the same dose level you received the first time or a lower dose.

Several studies suggest that the infused T cells need room to be able to proliferate and accomplish their functions and that this may not happen if there are too many other T cells in circulation. Because of

Patient Name/ID #: _____
Protocol Version 8.2

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TREATMENT CONSENT FORM

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H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

that, if your level of circulating T cells is relatively high, you may receive treatment with cyclophosphamide (Cytoxin) and fludarabine (chemotherapy drugs) before you receive the T cells. This will only occur if the study doctor feels you are well enough to receive these medications. These drugs will decrease the numbers of your own T cells before we infuse the T cells. Although we do not expect any effect on your tumor with the dose that you will receive, this drug is part of many regimens that are used to treat lymphoma or leukemia. If you are already receiving chemotherapy, this may not be needed.

If your circulating T cells are relatively high prior to any additional dose of T cells you may receive treatment with cyclophosphamide and fludarabine before the additional doses of T cells.

The treatment will be given by the Center for Cell and Gene Therapy at Texas Children's Hospital or Houston Methodist Hospital.

Medical tests before treatment--

Before being treated, you will receive a series of standard medical tests:

- Physical exam and History
- Blood tests to measure blood cells, kidney and liver function
- Pregnancy test for females of childbearing potential
- Measurements of your tumor by scans and/or bone marrow studies

Medical tests during and after treatment--

You will receive standard medical tests when you are getting the infusions and after:

- Physical exams and History
- Blood tests to measure blood cells, kidney and liver function
- Measurements of your tumor by scans and/or bone marrow studies 6 to 8 weeks after the infusion

To learn more about the way the CD19 chimeric receptor-T cells are working and how long they last in the body, extra blood will be drawn. The total amount on any day is about 10 teaspoons (50 mL). This volume is considered safe but may be decreased if you are anemic. For children, the total amount of blood drawn will not be more than 3 mL (less than 1 teaspoon) per 2.2 lbs of body weight. This blood may be drawn from a central line if you have one. On the day you receive the cells, blood will be taken

Patient Name/ID #: _____
Protocol Version 8.2

CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT FORM

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H-33133- CARPASIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

before the cells are given and several hours afterwards. Other blood will be drawn one week after the infusion, 2 weeks, 3 weeks (this one is optional), 4 weeks, 6 weeks, and 8 weeks (this one is optional) after the infusion, at 3 months, at 6 months, at 9 months, at 1 year, every 6 months for 4 years, then yearly for a total of 15 years. The total blood drawn during your participation in this study will not exceed 280 teaspoons.

During the time points listed above, if the T cells are found in your blood at a certain amount an extra 5ml of blood may need to be collected for additional testing.

If you develop GVHD of the skin we may photograph it for diagnostic purposes and to follow your response to treatment. You will sign a separate consent before we take photos of you.

If you have a biopsy of your tumor or bone marrow studies while you are on this study, we may ask to have a piece of tumor or bone marrow to look for CD19/CD28 chimeric receptor-T cells.

Leftover specimens and information about your circumstances may be used in other research being conducted in immune therapy. Although there will be a record identifying under what circumstances these specimens were obtained, under all circumstances your identity will be kept confidential. There is a small risk for the loss of confidentiality. However, study personnel will make every effort to minimize this risk.

If you decide to withdraw at any time during the study, data collected during your participation will be maintained. Samples collected for safety assessments will also be maintained per FDA requirements. Any leftover samples that were kept for future research will be maintained unless you request that the samples be destroyed.

In the event of your death, we will request permission to perform an autopsy to learn more about the effect of this experimental treatment on your tumor. This consent form is not legally binding and proper consent for an autopsy will be obtained from your next of kin in the event of your death.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.

Patient Name/ID #: _____
Protocol Version 8.2

H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, TCH: Texas Children's Hospital, TMH: The Methodist Hospital, and BAYLOR COLLEGE OF MEDICINE (BCM) and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific

Patient Name/ID #: _____
Protocol Version 8.2

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**TREATMENT CONSENT FORM**

H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

institution where you are being enrolled into this research study which are: Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, BAYLOR COLLEGE OF MEDICINE (BCM) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, Data and Safety Monitoring Board, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization .

To revoke this Authorization, you must write to: Carlos Ramos, MD, Feigin Center, 1102 Bates Street, Suite 1760, Houston, TX 77030.

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

While on this research study you are at risk for side effects from the treatments . There may also be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and less uncomfortable. Many side effects will go away shortly after treatment is stopped , but in some cases, side effects may be long lasting or permanent. Some side effects may be life threatening. Patients are watched carefully and treatment is stopped if serious side effects develop .

Side Effects of the CD19 Antibody and CD28

There are several antibodies that are similar to CD19 and have been given to patients with cancer. Some people who have received these antibodies have had temporary muscle and back pain, fever and chills, shaking, chest pain and labored breathing, wheezing, and nausea or vomiting. These side effects are unlikely in this study where the antibody is stuck to the T cells . One other side effect is that the antibody may react with normal cells such as normal immune system cells called B cells that have CD19 on their surface as well as the cancer cells. If the CD19 chimeric receptor-T cells worked very well they could kill your normal B cells as well as the lymphoma and leukemia cells. In that case you would not have B cells to make antibodies that help you fight infection and may have a higher risk of some types of infection. We will check your antibody levels and if these are low we will replace with a product called IVIG that contains antibodies. You would need to get IVIG every 6-8 weeks. There are no known side effects of CD28.

Patient Name/ID #: _____
Protocol Version 8.2

H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

Side Effects of the T cells

Similar types of T cells have been given to patients with cancers and infections. Usually the patients have no problems with the infusions. With the increased doses of T-cells, there is a possibility that the harmful effects could increase, though in previous studies we have seen very minimal problems. In some patients with large tumors the cells have caused inflammation leading to fever and flu-like symptoms as well as swelling within the tumor. This swelling and inflammatory reaction could be potentially dangerous and even life threatening depending on the site and size of the tumor.

CD19 CAR T cells when used in patients with lymphoma and chronic leukemia are known to cause side effects. Common side effects include Cytokine Release Syndrome (CRS) and neurotoxicity. Details of these side effects follow:

CRS is a group of symptoms associated with the release of substances that cause inflammation called cytokines into the blood circulation. CRS can affect many different parts of the body, and most patients will have at least some of the symptoms listed below. Severe or life-threatening cases requiring life support (intensive care), blood pressure medications, dialysis, or ventilators (breathing machines) have occurred in approximately 25% of subjects. Specific symptoms have included:

- General: fever and tiredness
- Heart: rapid or irregular heart rate, decreased heart function, cardiac arrest, heart muscle injury, or very low blood pressure. These events may be life threatening and require special medications or procedures to restore blood circulation including CPR.
- Lungs: shortness of breath and low oxygen supply sometimes requiring supplemental oxygen and/or insertion of a breathing tube and placement on a ventilator (breathing machine) to help with breathing
- Blood vessels: vascular leak syndrome (in which the fluid in your bloodstream leaks out of circulation into other areas of your body)
- Kidneys: low urine output and kidney failure, sometimes requiring dialysis
- Stomach/liver/intestines: liver dysfunction (e.g., changes in AST/ALT), nausea, vomiting, diarrhea

Neurotoxicity is a group of symptoms involving the brain and spinal cord. Most patients will have at least some of the symptoms listed below. Severe or life-threatening cases have occurred in approximately 25% of subjects. Specific symptoms have included confusion, difficulty speaking or understanding speech, prolonged or pronounced sleepiness, tremors (shaky hand or other body part), facial droop, seizures which may be prolonged, inability to control bladder or bowel, weakness in arms and/or legs, difficulty or inability to walk, anxiety and dizziness. Neurotoxicity can also lead to difficulty breathing and low oxygen levels, requiring insertion of a breathing tube and placement on a ventilator (breathing machine) to assist with breathing and may be potentially life-threatening.

In addition to the above-mentioned supportive medical care for patients who develop CRS and/or Neurotoxicity, medications will be used that specifically treat both conditions.

H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

As you are receiving donor T cells after a stem cell transplant from a related or unrelated donor, there is the possibility that these donor T cells might try to attack other parts of your body and cause graft versus host disease (GVHD). GVHD occurs when cells from your bone marrow donor (graft) recognize that your body's tissues (host) are different from those of the donor. When this happens, cells from the donor may attack your skin, liver and/or intestines. If you have GVHD after the transplant you may not be able to get the cells. If you have GVHD after the T cells have been given, we will treat you appropriately.

Side Effects of the Gene Transfer

To get the antibody to attach to the surface of the T cell, we must deliver the gene for the antibody into the T cells. This is done with a virus called a retrovirus that has been made for this study. The retrovirus has been altered so it should not be able to come out of the T cells and infect other cells. When retroviral vectors enter a normal cell in the body, the gene it carries goes into the DNA (genetic material) of the cell. Human DNA contains thousands of genes. When the retrovirus adds the gene it carries into the human DNA this is called integration. Integration can occur anywhere in DNA and most integration does not harm the cell or the study subjects. However, there is a chance that there may be some parts of human DNA where integration may turn on other genes. For example, if it turned on a gene that made a substance that caused the cell to grow it might cause uncontrolled increase in the numbers of cells, which could result in cancer. There was one study in mice where cancer occurred, but most other animal studies have shown this risk to be very low with the type of retrovirus we are using.

Some patients who have received marrow stem cells modified with retroviral vectors to correct immunodeficiency disorders have developed leukemias that are due to the vectors. To date this has only been seen in patients being treated who have received stem cells treated with retroviral vectors for immunodeficiency conditions. No leukemias or other cancers have been seen in hundreds of patients who have received T cells modified with retroviral vectors. However, the risk of developing cancer is a risk of receiving products that contain a retroviral vector.

Side effects of lymphodepletion chemotherapy with cyclophosphamide and fludarabine:

Risks and side effects related to cyclophosphamide include:

Likely:

Loss of appetite, Nausea; Vomiting; Fewer white blood cells in the blood (A low number of white blood cells may make it easier to get infections); Hair loss; Decreased ability of the body to fight infection; Absence or decrease in the number of sperm which may be temporary or permanent which may decrease the ability to have children.

Less likely:

Abnormal hormone function which may lower the level of salt in the blood; Abdominal pain; Diarrhea; Fewer red blood cells and platelets in the blood; A low number of red blood cells may make you feel tired and weak; A low number of platelets may cause you to bruise and bleed more easily; Bleeding and

Patient Name/ID #: _____
Protocol Version 8.2

CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT FORM

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H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

inflammation of the urinary bladder; Absence or decrease of monthly periods which may be temporary or permanent and which may decrease the ability to have children; Temporary blurred vision; Nasal stuffiness with IV infusions; Skin rash; Darkening of areas of the skin and finger nails; Slow healing of wounds; Infections.

Rare but serious:

Heart muscle damage which may occur with very high doses and which may be fatal; Abnormal heart rhythms; Damage and scarring of lung tissue which may make you short of breath; A new cancer or leukemia resulting from this treatment; Damage or scarring of urinary bladder tissue; Severe allergic reaction which can be life threatening with shortness of breath, low blood pressure, rapid heart rate, chills and fever; Infertility which is the inability to have children.

Risks and side effects related to fludarabine include:

Likely (may happen in more than 20% of patients):

Low number of red blood cells (anemia); Low number of white blood cells; Low number of blood platelets; Feeling tired; Nausea (feeling sick to your stomach); Throwing up (vomiting); Weak immune system; Pneumonia; Infection; Bleeding; Pain; Electrolyte imbalance.

Less likely (may happen in fewer than 20% of patients):

Diarrhea; Mouth sores; Skin rash; Fever; Swelling of hands and feet; Numbness and tingling in hands and/or feet; Loss of appetite.

Rare but serious (may happen in fewer than 2% of patients):

Changes in vision; Feeling nervous or anxious; Confusion; Cough; Difficulty breathing; Feeling weak; Severe brain injury which can lead to death; Kidney damage that could require dialysis; Coma; New (secondary) cancers

Risks of Acetaminophen (Tylenol):

Rarely large doses or long term usage can cause liver damage, rash, itching, fever, lowered blood sugar. These side effects are unlikely at the doses being used for this study.

Risks of Benadryl (Diphenhydramine):

Drowsiness, dizziness, headache, irritability, stomach upset, vision changes (e.g., blurred vision), decreased coordination, or dry mouth/nose/throat may occur.

Because of potential or unknown effects of the study on a fetus, if you are a woman of childbearing potential, you must have a negative serum pregnancy test prior to entry into this study.

You have been informed that either you or your partner(s) must utilize one of the more effective birth control methods during the study and for six months after the study is concluded. These consist of total

Patient Name/ID #: _____
Protocol Version 8.2

CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT FORM

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H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

abstinence, oral contraceptives "the pill", intrauterine devices (IUDs), contraceptive implants under the skin, or contraceptive injections. If one of these methods cannot be used, contraceptive foam with a condom is allowed. In addition, the male partner should use a condom.

Since this is a research study, there may be risks that are currently unknown. We will watch you very carefully for any side effects. If there are bad side effects, we will stop the treatment.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: that your immune system may begin to kill the cancer cells. This could make the cancer grow more slowly, or get smaller, or go away for a while. This benefit is at best only possible, and may not happen to you. This type of study is not designed to provide a benefit to you, however, your participation may help us better understand how the immune system can fight this disease. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: other treatments with chemotherapy, radiation, or surgery. Your doctor will discuss these other options with you. Additionally, the same alternatives are available if, after participation in this research project, you are not responding to the therapy. You may also choose to receive no further treatment for your tumor. If this is your decision, your doctor will help manage your symptoms and will discuss this with you.

Subject Costs and Payments

You will not be charged for the manufacture or production of the CD 19/CD28 chimeric receptor T cells, nor will you be charged for the laboratory studies done to monitor the how well these T-cells are working and to measure how long they stay in your body. You and/or your insurance company may be charged for some research related costs including the infusion of the product. You and/or your insurance company will be responsible for medical services provided that are part of the standard of care for your cancer.

You will not be paid for taking part in this study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Research Related Injury

If you are injured as part of your participation in this study, there are no plans to pay you.

Patient Name/ID #: _____
Protocol Version 8.2

CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT FORM

HIPAA Compliant

H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, CARLOS RAMOS, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: CARLOS ALMEIDA RAMOS at 832-824-4817 during the day and 713-441-1450 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

The National Institutes of Health and the National Cancer Institute may have access to your records for research purposes. Coded information may be provided to the NIH/NCI such as Patient ID, Patient Zip code, Patient country code and Patient Birth date (month/year). However, in the event of an audit NIH/NCI might have access to more information that is part of your research record.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

ADULT ASSENT (as applicable)

If the person you represent is the one invited to take part in this study, you are signing to give your permission. Each adult who lacks the capacity to consent may agree to take part in a study at his or her own level of understanding. When you sign this, you also note that the person you legally represent understands and agrees to take part in this study according to his or her understanding.

Patient Name/ID #: _____
Protocol Version 8.2

CONSENT FORM

HIPAA Compliant

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**TREATMENT CONSENT FORM**

H-33133- CARPASCIO: PHASE I STUDY OF ACTIVATED T LYMPHOCYTES EXPRESSING CHIMERIC ANTIGEN RECEPTORS FOR THERAPY OF RELAPSED CD19-POSITIVE MALIGNANCIES POST-ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION INFUSED ONLY AFTER ENGRAFTMENT

Please print the person name you legally represent here _____.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here _____

Patient Name/ID #: _____
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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Legally Authorized Representative Parent or Guardian	Date
Legally Authorized Representative - Adult	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date

Patient Name/ID #: _____
Protocol Version 8.2