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UNIVERSITY OF WASHINGTON SCHOOL OF MEDICINE
DEPARTMENT OF MEDICINE, DIVISION OF ONCOLOGY
AND THE FRED HUTCHINSON CANCER RESEARCH CENTER

Consent Form for Use of Monoclonal T-cell Antibody (mcAb) for Removal of T-Cells from Donor Marrow

Investigators: P.J. Martin (292-6545), J.A. Hansen, E.D. Thomas, and Members of the Division of Oncology. Emergency Phone (24 hours): 467-4369.

Attending physician: _____ Phone: _____

Investigators' Statement

PURPOSE AND BENEFITS

Patients undergoing marrow transplantation are at risk to develop graft-versus-host disease (a reaction of the donor cells against recipient's tissues). This complication may vary from a mild skin rash to a severe form involving the skin, liver and/or gut and may be fatal. The immunological reaction that we identify as graft-versus-host disease is caused by certain cells called T-cells in the donor marrow that recognize the host as "foreign". Previous studies here and elsewhere have shown that removal of T-cells from the donor marrow can decrease the incidence of graft-versus-host disease after marrow transplantation. T Cell depletion can be accomplished by using a relatively new form of very specific antibodies (monoclonal T-cell antibodies). You will also receive a medication called Methotrexate as a further means of controlling graft-versus-host disease. Most patients have been given this drug intermittently until day 100 after transplantation. Since you will be receiving marrow depleted of cells that cause graft-versus-host disease, you will be given only the first four doses (on days 1, 3, 6 and 11) after transplantation. A second reason for giving Methotrexate is that it may help to prevent graft failure.

PROCEDURES

Bone marrow will be removed from the donor in the usual fashion. After processing to remove most of the red cells, the bone marrow will then be incubated with monoclonal T-cell antibody and with rabbit serum which provides factors necessary to kill T-cells coated with antibody. The monoclonal antibody and rabbit serum will be removed from the bone marrow before infusion. Methotrexate will be infused through the Hickman line. Twenty ml (about 4 tablespoonfuls) of blood will be collected from the patient prior to receiving antibody treated bone marrow.

RISKS, STRESS OR DISCOMFORT

The use of monoclonal antibody in human patients is still investigational and with any such product there may be unanticipated adverse effects. There is a possibility of an allergic reaction even though nearly all of the monoclonal antibody and the rabbit serum will have been removed. Other possible effects are fever, chills, temporary difficulty in breathing or drop in blood pressure. Your clinical situation will be monitored closely at all times. Treatment of marrow with monoclonal antibody and rabbit serum may damage cells necessary for engraftment, and it is possible that failure of engraftment or graft rejection may occur following such treatment. In this case, a second marrow transplant would be necessary. It is possible that clinically significant graft-versus-host disease could occur despite removal of T cells from the donor marrow. In this case, you would be treated with appropriate immunosuppressive medications. Methotrexate, together with cyclophosphamide and total body irradiation may cause mouth sores which will heal within several weeks after transplantation. Additional risks associated with Methotrexate are outlined in the consent form for the main patient treatment protocol.

"possible" - 25% + reported
2nd transplant - 0% success

OTHER INFORMATION

The antibody will have been prepared in mice. If you are aware of any allergies to these animals you should let your physician know of this. Participation in this form of therapy is voluntary and you may withdraw at any time without prejudice.

The physicians caring for you will advise you if there are new findings regarding alternate treatments or toxicity.

This study will be conducted as described in the basic oncology consent form and the other consent forms associated with protocol assignment.

Signature of Investigator _____ Date _____

Subject's Statement

I agree to this study and to the conditions described in the basic oncology consent form which I have read and signed. I am aware that I and/or my insurance carrier is responsible for the costs incurred in the therapy provided, including adverse effects. I acknowledge receipt of a signed copy of this consent form.

Witness _____ Adult Patient _____

Mother _____ Minor Patient _____

Father _____ Date _____

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copies to: Patient
Medical records
Research file