

Treatment of Late Isolated Extramedullary Relapse from Acute Lymphoblastic Leukemia (ALL) (initial CR1 > 18 Months) (AALL02P2)

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Synopsis:

The patients in this clinical trial have a type of cancer known as acute lymphoblastic leukemia (ALL) which has relapsed (returned) in their central nervous system (brain and spinal cord) and/or their testes.

Currently, the standard treatment for ALL that has relapsed in this manner includes radiation therapy to the testes and/or brain along with chemotherapy. The goal of this study is to discover whether reducing the amount of radiation to the brain and eliminating radiation to the testes will still produce the same high rates of remission (ALL can no longer be detected by medical tests) found with standard treatment, but with fewer side effects. This may prove to be true.

However, the study might also show that less radiation to the brain and no radiation to the testes may not produce the same results as standard radiation. In this case, treatment on this study may prove to be worse than standard therapy.

The chemotherapy drugs used on this study are the same as those that are used in the standard treatment, but we will be using a more intense treatment. This may result in more or stronger side effects.

The treatment on this study will consist of several phases. In the first phase, called induction, we try to remove all visible signs of leukemia and allow normal blood cells to be restored. In the middle phases, called consolidation, intensification I, reinduction, and intensification II, we try to deliver a "knock-out" punch to the remaining leukemia cells. In the final phase, called maintenance, we try to keep the leukemia from coming back (disease remission).

Patients with testicular relapse will also receive a single high dose of Methotrexate chemotherapy two weeks before they start induction. If a patient still has leukemia in his testes after he has completed induction chemotherapy, he will be given radiation therapy to his testes before receiving any more chemotherapy.

Radiation to the testes is likely to affect both fertility and hormone production. Most patients who have this form of treatment will not be able to father children later on. Some may need to take hormones.

Patients with central nervous system (CNS) relapse will receive radiation to their brain after induction and before consolidation.

Radiation to the brain may produce the following side effects: hair loss, which may take six months or more to grow back; reddening of the skin; possible nausea and/or loss of appetite; and lowered white blood cell counts (which can increase the risk of infection) and platelets counts (which can increase the risk of excessive bleeding). There is also a risk of temporary worsening of neurological symptoms, such as weakness or loss of sensation. Some patients experience a week or two of low grade temperature and extreme sleepiness six to eight weeks after radiation

has been completed. With radiation there is also the small chance that a second tumor (for example a brain tumor) may appear years later at the site of treatment.

All phases of treatment are very important. The total length of time on this study is about two years.

Patients who have leukemia in their central nervous system may experience varying degrees of changes in learning, behavior, attention and concentration. Radiation to the brain can also produce these types of changes. In order to study these effects over a long period of time, researchers would like to do a number of tests on all patients on this study to measure any differences between the patients who have relapsed in their brain and patients who have relapsed in their testes.

The testing would take place within three months after completing induction therapy (and before any radiation to the brain is given), and then again within two years after the treatment is finished. These tests will include age appropriate measures of learning, memory, attention span and hand-eye coordination. Measurements of behaviors will also be included.

The chemotherapy used in this study can produce unwanted side effects. These risks may also occur on standard leukemia therapy and are not necessarily restricted to participation in this study.

Chemotherapy agents are drugs that, in addition to killing tumor cells, can damage normal tissue and produce side effects. The common side effects from cancer treatment include nausea, vomiting, hair loss and low blood cell counts, but more serious side effects can occur. These side effects are usually reversible when the medications are stopped, but occasionally they can continue and cause serious complications. The use of chemotherapy may lead to the inability to have children. Sometimes patients may die as a result of serious side effects that cannot be reversed. There is also the slight possibility that a second cancer may develop years later as a result of the chemotherapy.