A Phase III Study of Reduced Therapy in the Treatment of Children with Low and Intermediate Risk Germ Cell Tumors (AGCT0132)

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Synopsis:
A germ cell tumor is a type of cancer found in the ovaries (females) or the testes (males). This tumor may also be found in other areas of the body such as the brain, chest or abdomen.

A low risk germ cell tumor has the following characteristic:
- it is present only in the testes or ovaries and is completely removed by surgery (Stage 1).

The standard therapy for patients who have low risk testicular tumors is surgery and observation (to watch for a certain amount of time). The standard therapy for patients with low risk ovarian tumors is surgery plus chemotherapy (treatment with anti-cancer drugs) given four times (for 5 days each time).

An intermediate risk germ cell tumor has one of the following characteristics:
- it is present only in the testes or ovaries, but is not completely removed by surgery (Stage 2).
- it is present in the testes or ovaries and also has spread to the lymph nodes or other nearby organs (Stage 3).
- it is present in the testes and has spread to a distant site in the body (Stage 4).
- it is present in a location outside of the ovaries or testicles and was either completely removed or nearly completely removed by surgery (tumor not visible to the surgeon’s eye remains) and does not involve lymph nodes nor has it spread to other organs (Extragonal Stage 1 or 2).

The standard therapy for patients with intermediate risk germ cell tumors is surgery plus chemotherapy given four times (for 5 days each time).

The primary purposes of this study are:
- To avoid chemotherapy in low risk testicular/ovarian germ cell tumors by using surgery and observation. We would use chemotherapy only if the tumor returns or the tumor markers fail to return to normal levels.
- To decrease the total amount of chemotherapy given (three times instead of four) for those patients receiving chemotherapy.
- To decrease the number of days over which the chemotherapy is given from 5 to 3 days in each treatment cycle.
- To determine what genetic factors may be in malignant (cancerous) germ cell tumors and the blood of patients with these tumors.