

# A Phase III Group Wide Study of Dose Intensive, Response Based Chemotherapy and Radiation Therapy for Children and Adolescents with Newly Diagnosed Intermediate Risk Hodgkin's Disease (AHOD0031)

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## Synopsis:

### Background/Aims:

Treatment for Hodgkin disease using drugs (chemotherapy) and high-dose x-rays (radiation therapy) has been very successful but there are possible significant negative effects from the treatment later in life. These effects (such as problems with growth, organ function, or even development of a second cancer) are called late effects. The goal of this study is to design treatment based on the tumor response so that patients can receive fewer drugs and lower doses of radiation therapy but still have the same high rate of cure and fewer late effects.

This clinical trial looks at whether some patients, who respond very well to treatment early on (rapid early responders), can be given treatment that does not include radiation without losing any treatment benefit. To accomplish this, some rapid early responders will be given treatment without radiation therapy while others will be given standard treatment (which includes radiation therapy). The treatment arm that does not include radiation therapy is considered an experimental arm of treatment.

Some patients, however, do not respond as well to the first stages of treatment (slow early responders). Slow early responders are considered to be at higher risk for relapse. This study also looks at whether these kinds of patients will benefit from additional chemotherapy. To accomplish this, some slow early responders will be given treatment with additional chemotherapy while others will be given standard treatment (which includes the standard amount of chemotherapy). The treatment arm with additional chemotherapy is considered an experimental arm of treatment.

In addition, there is an optional biology part of this study to see how patients respond to treatment. Taking part in the biology study, requires up to five blood draws during months of treatment and one blood draw after treatment.

### Eligibility:

- Newly diagnosed pathologically confirmed Hodgkin disease;
- The disease is contained in only one or two areas of the body;
- Up to and including 21 years of age at diagnosis;
- Must enroll within 28 days of diagnosis or staging;
- Must agree to randomization during therapy;
- No previous therapy for this cancer; and
- Patient's organ function tests must meet study requirements.

### Study Design:

Patients are asked to agree to be randomized to either standard therapy or experimental therapy.

All patients begin treatment on this study with two 21-day cycles of ABVE-PC chemotherapy (an outline of ABVE-PC chemotherapy is provided below). Patients will then be evaluated for their response to treatment. Patients with disease reduction less than 60% are put in the group of

Slow Early Responders (SERs). The next step for patients who are SERs is determined by randomization to either receive 2 cycles of DECA chemotherapy (an outline of DECA chemotherapy is provided below) plus 2 cycles of ABVE-PC chemotherapy or 2 cycles of ABVE-PC chemotherapy only. Patients who are SERs then complete treatment with radiation therapy to areas of the body affected by the cancer.

Those patients evaluated as having an early response to treatment will be put in the group of Rapid Early Responders (RERs). The RER group includes those patients whose disease has been reduced by 60% or more. The next step for patients with RERs is 2 more cycles of ABVE-PC chemotherapy followed by another evaluation of their response. Those determined to have a complete response (at least an 80% disease reduction) will be randomized to receive radiation therapy to areas of the body effected by the cancer (Standard therapy arm) or to receive no radiation therapy (Reduced therapy arm). Those patients determined to have less than a complete response, will not be randomized and will automatically be assigned to receive radiation therapy.

#### Potential Side Effects:

The side effects from the drugs and radiation used to treat Hodgkin disease on this study are the same as those that would occur with standard therapy. For those randomized to receive the DECA chemotherapy there may be additional side effects. There will be some risk associated with participation in this study since we do not know if the reduced total dose of drugs and radiation are as effective as the standard doses in treating the disease.

Participation in this study is voluntary and patients may withdraw at any time for any reason. Doctors running the study also may remove patients from study treatment at any time if they believe it is in the patients' best interest to do so.

If patients and their families would like more detailed, technical information about this trial, they should contact their treating physician, the physician in charge of the study at their hospital, or the Study Chair.