COG-ALTE03N1: Key Adverse Events after Childhood Cancer

FAST FACTS
Eligibility Reviewed and Verified By
______________________ MD/DO/RN/LPN/CRA Date ____________
______________________ MD/DO/RN/LPN/CRA Date ____________
Consent Version Dated___________

PATIENT ELIGIBILITY:
Important note: The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01).
Cases will consist of patients experiencing a key adverse event, who meet the following criteria:

___1. Diagnosis of any primary cancer at age 21 or younger, irrespective of current age
___2. No prior history of allogeneic (non-autologous) hematopoietic cell transplant
___3. Development of one of the following key adverse events at any time following initiation of cancer therapy (see Section 4.1 for definitions):
   • Cardiac dysfunction (CD)
   • Ischemic stroke (IS)
   • Subsequent malignant neoplasm (SMN)
   • Avascular necrosis (AVN)
___4. Willing to submit a blood sample (or in certain cases a saliva sample) to the Coordinating Center Laboratory per the requirements outlined in Section 4.4.*
   *Please Note: If a patient is currently receiving active cancer treatment, it is preferable to obtain the blood sample at a time when the patient’s WBC is >2,000
___5. Written informed consent from the patient and/or the patient’s legally authorized guardian.
___6. In active follow up by a COG institution.
   Active follow up will be defined as date of last visit or contact by a COG institution within the past 24 months. Any type of contact, including contact specifically for participation in ALTE03N1, qualifies as active follow-up.
   Please Note: Treatment on a COG (or legacy group) therapeutic protocol for the primary cancer is NOT required.

The CIRB has determined that assent of children age 7 and older is required.

Eligibility criteria for controls:
___1. Diagnosis of primary cancer at age 21 or younger, irrespective of current age
___2. No prior history of allogeneic (non-autologous) hematopoietic cell transplant
___3. No clinical evidence of any of the following key adverse events:
   • Cardiac dysfunction (CD)*
   • Ischemic stroke (IS)
   • Avascular necrosis (AVN)
   • Subsequent malignant neoplasm (SMN)
___4. Willing to submit a blood sample (or in certain cases a saliva sample) to the Coordinating Center Laboratory as per the requirements outlined in Section 4.4.*
   *Please Note: If a patient is currently receiving active cancer treatment, it is preferable to obtain the blood sample at a time when the patient’s WBC is >2,000.
___5. Written informed consent from the patient and/or the patient’s legally authorized guardian, obtained in accordance with institutional policies approved by the U.S. Department of Health and Human Services.
___6. In active follow up by a COG institution.
   Active follow up will be defined as date of last visit or contact by a COG institution within the past 24 months. Any type of contact, including contact specifically for participation in ALTE03N1, qualifies as active follow-up.
   Please Note: Treatment on a COG (or legacy group) therapeutic protocol for the primary cancer is NOT required.
Definition of Key Adverse Events

1. Cardiac dysfunction (CD)
   Cardiac dysfunction will be defined as follows:
   • **Symptomatic Cardiac Dysfunction** – current or previous diagnosis of congestive heart failure (based on clinical criteria such as pulmonary and/or peripheral edema, dyspnea, orthopnea, fatigue, hepatomegaly, rales).
   OR
   • **Asymptomatic Cardiac Dysfunction** defined as ejection fraction < 40% on echocardiogram or MUGA and/or fractional shortening < 28% on echocardiogram without clinical symptoms.

2. Ischemic Stroke (Stroke)
   Ischemic stroke will be defined as:
   • A fixed neurologic deficit lasting for more than 24 hours, **AND**
   • Confirmation by a computed tomography or magnetic resonance imaging scan within seven days of onset of symptoms.
   *Subarachnoid and intracerebral hemorrhage, transient ischemic attacks, and amaurosis fugax will be excluded.*

3. Avascular Necrosis (AVN)
   Diagnosis of avascular necrosis will be made by:
   • Clinical symptoms of joint pain, joint stiffness, or decreased range of motion **AND**
   • Radiographic confirmation (e.g. plain radiographs, computerized tomography, magnetic resonance imaging, bone scan)

4. Subsequent Malignant Neoplasm (SMN)
   Subsequent malignant neoplasms will be defined as:
   • Histologically distinct neoplasms developing in patients treated for a primary cancer, **AND**
   • Institutional pathology report confirming diagnosis of SMN

REQUIRED OBSERVATIONS:
No specific pre-study observations required.

TREATMENT PLAN:
This is a data collection study

TOXICITIES AND DOSAGE MODIFICATIONS:
None

SPECIMEN REQUIREMENTS:
Peripheral blood - Blood drawn at regularly scheduled follow-up appointments
Whenever feasible, peripheral blood will be obtained from consenting study participants at their regularly scheduled follow-up appointments. Self-explanatory blood draw kits will be sent by the coordinating center to each participating institution. Each kit will contain instructions, blood sampling tubes, and mailing supplies. *Please Note: Receiving institutions are strongly encouraged to make requests for sample collection kits at least two weeks in advance of their anticipated patient registration on ALTE03N1.*

See Section 4.4.2 for Saliva Sample collection