Clinical Study to Test Safety of a Virus Therapy in Children and Young Adults with Recurrent or Refractory Solid Tumors (Excluding Brain Tumors)

Family Friendly Version

Purpose of the Study

Cincinnati Children's Hospital Medical Center is conducting a research study, sometimes known as a clinical trial or clinical study, to test how safe and well tolerated the study drug is in children and young adults with certain cancers. Researchers want to see what effects - good or bad - the study drug HSV1716 has when injected into tumors. HSV1716 is derived from the herpes simplex virus that causes fever blisters or cold sores, but has been partially crippled similar to a live virus vaccine. While HSV1716 is not thought to cause problems like cold sores, it can still grow in and destroy cancer cells.

Who will be included in this study?

Children, teenagers and young adults 13 to 30 years old who have been diagnosed with a cancer that has not responded to standard therapy or for which no standard therapy exists may be eligible to participate.

What is involved?

Participants will be evaluated for eligibility and feasibility of tumor injection. If accepted into the study, there will be several outpatient visits and an overnight inpatient stay required. Visits may include the following:

- Physical Exams
- Electrocardiogram (EKG) to measure the electrical activity of the heart
- Chest X-ray
- Tumor imaging to find the primary tumor site and to see if it has spread to other parts of the body
- Injection of study drug (HSV1716) into the tumor
- Blood tests for the presence of infectious disease, to screen for possibility of pregnancy in females, to check blood counts, etc.
- Blood tests to check for the presence of the herpes simplex virus (HSV)
- Buccal swabs - swabs from the inside of the mouth - to check for HSV
- Urine tests to check kidney function

Participants will be in this study up to 15 years, which is the length of time the FDA currently recommends for following individuals who receive this type of experimental agent. There will be approximately 13 study visits during the first year, 2 visits a year for five years, and approximately 1 visit a year thereafter.

Benefits

It is not known whether treatment with HSV1716 will have any affect on the cancer or if participants will receive a direct medical benefit. HSV1716 could cause the cancer to stop growing, the tumor to get smaller for a period of time, or lessen symptoms, but it is also possible that the cancer could continue to become worse despite taking this study drug.

Facts About the Study

Participants will be given a consent form that thoroughly explains all of the details of the study. The form covers all of the procedures, the risks, the benefits, the pay, who to contact with questions or concerns and more. A member of the study staff will review the consent form with you and will be sure that all of your questions are answered. Study procedures will not begin until the patient or if <18 years old, a parent or guardian, has given consent.

Discomforts

A detailed list of risks and discomforts will be provided to those interested in knowing more about this study.

Pay

Study participants will not be compensated but will receive the study drug HSV1716, the virus injection and the special HSV studies free of charge.

Contact Information

Principal Investigator
Timothy P. Cripe, MD, PhD
Professor of Pediatrics
Division of Hematology/Oncology
Cincinnati Children's Hospital Medical Center
timothy.cripe@cchmc.org
513-636-4171

Rebecca Turner, MS, CCRP
Rebecca.turner@cchmc.org
513-636-9419
Clinical Research Manager
Division of Hematology/Oncology
Cincinnati Children's Hospital Medical Center