Research Opportunity Inquiry
Clinicaltrials.gov - NCT03923257
Dosimetry Guided PRRT With 177Lu-DOTATATE in Children and Adolescents

1.Please list the names and contact information for researchers.

M. Sue O'Dorisio, MD, PhD
University of Iowa Department of Pediatrics
1300-28 BT, 200 Hawkins Drive
Iowa City, IA 52242
Sue-odorisio@uiowa.edu
Phone: 319-356-3595 Office
Phone: 319-855-2151 Cell

Yusuf Menda, MD
University of Iowa Department of Radiology
200 Hawkins Drive
Iowa City, Iowa 52242
Yusuf-menda@uiowa.edu

2.Please provide a brief "lay language" summary of the research, including the title of the study and its time frame.

Pheochromocytoma and paraganglioma are very rare in children, but for those children who have disease that requires treatment, there are very few options. Recent studies have determined that these tumors often have proteins on the surface of the tumor cells called somatostatin receptors. Therapy targeted to these cells, called 177Lu-DOTATATE (also called Lutathera®) is approved by the FDA for treatment of adults, but not for children or adolescents under the age of 18 years. The University of Iowa has a clinical trial that permits children with metastatic pheochromocytoma or paraganglioma to receive this therapy.

3.Has the study received ethics clearance from a hospital or university IRB? Please identify the IRB(s) and date of clearance.

This clinical trial was written by Drs. O'Dorisio and Menda; it has been approved by the University of Iowa IRB as of July 20, 2020.

4.What is the funding source and funding duration for the research?

The pharmaceutical company that provides Lutathera® for all hospitals in the United States is Advanced Accelerated Applications (AAA); it is a division of Novartis Pharmaceuticals. AAA is providing the Lutathera® free of charge and is supporting the cost of the trial.

5.What are potential patient participants being asked to do as part of this study (e.g., fill in a survey, be interviewed, keep a journal)?

Parents and the child, as well as their doctor, would receive a copy of the protocol for the trial and would first decide if the child or adolescent wants to participate. If the child is enrolled, he/she would answer a quality of life questionnaire before and after the treatments. The child would receive the Lutathera® treatments at the University of Iowa Hospital and would have scans on Days 1,2,3,5

and 7 after each of the four treatments which are given IV. The child would be asked to keep a diary of fluid intake from the day before each treatment to two days after each treatment to improve clearance of the excess Lutathera® from the body.

6.Are there any expectations for the PPA beyond distributing information about the study to potential participants?

No.

7.What recruitment information will you provide for distribution to potential participants?

We are not allowed to distribute information unless/until a family or their doctor contacts us. The trial is listed on clinicaltrials.gov

8.How will the research benefit individual participants, PPA, and/or the medical/scientific community?

Each individual participant will receive the treatments free of charge, but we do not know if any participant will receive benefit. By participating in the trial, these children will help the FDA decide if all children with pheochromocytoma or paraganglioma should be allowed to have this drug, just like adults are already able to receive it.

9.How will individual participants and PPA receive feedback about the results of the study?

Each child/adolescent who participates in the trial will be told how their tumor responds to the treatment. The response of all patients together (approximately 35) will be published once the trial is complete.