What is the purpose of the study?
Diabetic ketoacidosis (DKA) is the most common presentation in children who develop type 1 diabetes mellitus (T1DM). DKA is the accumulation of ketone bodies in the body tissues and fluids. DKA can be very dangerous because it can cause a build-up of fluids in the brain called cerebral edema. Despite extensive research and investigation, the precise mechanism of cerebral edema in DKA remains unknown and a validated method for identifying or measuring the extent of the cerebral injury has not been identified. This study will focus on investigating the following potential biomarkers of cerebral edema in children with DKA: Endothelin-1 (ET-1), S100B, neuron-specific enolase (NSE) glial fibrillary acidic protein (GFAP) and total tau (tTau). These biomarkers have all been shown to be elevated in patients with cerebral injury from a variety of mechanisms. This study will look at the effect of insulin on serum levels of these biomarkers in children who have T1DM.

Who is eligible to participate in the study?
Children with established T1DM (with or without DKA) or newly diagnosed children with T1DM (with DKA) may be eligible to participate.

What does the study involve?
Eligible subjects will be divided into three groups. The study sample will include 100 subjects in the following three groups:

- **Group 1**: Children with established T1DM without DKA
- **Group 2**: Children with established T1DM with DKA
- **Group 3**: Children newly diagnosed with T1DM who present to the Emergency Department or Pediatric Intensive Care Unit (PICU) with DKA

Children in Group 1 will have blood drawn biomarker levels at the same time as their routine blood work. Children in Groups 2 and 3 will have four serial blood samples taken to evaluate the biomarkers:

- **Pretreatment**: The blood sample will be obtained before the patient is started on an insulin drip
- **4 (±1) hours after starting insulin drip**
- **8 (±1) hours after starting insulin drip**
- **24 (±2) hours after starting insulin drip**

Demographic information, vital signs and routine blood chemistry related to their treatment of DKA will be collected during the first 24 hours.

What are the benefits?
There is no guarantee of direct benefit for participation in this research study. However, information gained from this study may help other children with T1DM in the future.

What are the risks?
Risks of having blood drawn include some discomfort, bruising and rarely infection. Blood for the study will be obtained when subjects are having blood drawn for their routine care. The research study team will discuss all risks with interested participants prior to enrolling in the study.

Is there any compensation for participating?
There is no compensation for participation in this study.
How will I get more information about the study?
Interested parents will discuss the study with a member of the research team and will be given a parent permission/consent form that further explains all of the details of the study. Study procedures will not be started until the parent(s) fully understands what is involved in the study and has signed a parent permission/consent form.

Status: Recruiting
Site(s): Advocate Lutheran General Children’s Hospital

Who should I contact for more information?
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