Renal Anhydramnios Fetal Therapy (RAFT) Study

Renal Anhydramnios occurs when the fetus has a severe kidney problem in the womb. The kidneys make urine which becomes the main component of amniotic fluid at the beginning of the second trimester. In renal anhydramnios the kidneys do not make any urine, and therefore the fetus has no amniotic fluid. This fluid surrounds the fetus and performs many vital functions. The most important function is to allow the development of the lungs. If the kidneys stop making urine early in pregnancy, the fetus's chances of survival are very small. This situation is called Early Pregnancy Renal Anhydramnios (EPRA).

This research is being done to study EPRA and determine if repeated infusions of replacement amniotic fluid into the womb can rescue lung function at birth.

Study Outline

Patients with a tentative diagnosis of EPRA will be referred to a RAFT Center (see www.raft-trial.org for a list of RAFT centers). Patients will undergo testing and counseling by a RAFT center to determine if they qualify for the study. This study includes two groups:

Intervention Group: In this group, participants will undergo serial amnioinfusions (a needle will be inserted in the abdomen to infuse fluid) with fluid that mimics amniotic fluid. An expert fetal therapist will oversee this procedure by using ultrasound with local anesthesia at the RAFT center. These infusions will occur every 2-12 days. The participants will undergo fetal ultrasounds, MRIs, and echocardiograms to evaluate the fetal progress and will deliver at a RAFT center.

Expectant Management Group: Patients can also choose to be in the study but not receive the serial amnioinfusions. Some reports are unpublished of babies surviving without intervention. Participants who choose this method may feel the therapy is too experimental, unsafe, or just not right for them and their families. These participants will be helping science to better understand EPRA. Participants will receive serial ultrasounds, fetal MRIs, and fetal echocardiograms to collect data on the development of in-utero EPRA. Participants will be encouraged to deliver at a RAFT center but may deliver at their local hospital.

Important information:

Eligibility is time sensitive and your physician should refer you as soon as possible after a diagnosis.

Survivors with or without therapy will need significant medical care. They will have complete renal failure requiring dialysis and eventually a kidney transplant. They will require multiple surgeries and a prolonged NICU stay. If they survive to discharge from the hospital, they will need daily medical care for dialysis until they receive a kidney transplant. This is very challenging for any family, both from an emotional, social, and financial outlook.

For the intervention group, infant delivery and neonatal care will occur at the RAFT center. A licensed clinical social worker will be available to help with arrangements for participating at a nearby RAFT center, with funding available for relocation under special circumstances.

For the expectant management group, participants will have the option to be followed and deliver locally, but will be requested to return to the RAFT center for the 32 wk GA research evaluations. A travel stipend will be offered for this.

For more information on the RAFT trial

- www.raft-trial.org

- https://clinicaltrials.gov/ct2/show/NCT03101891