SLOW HEART REGISTRY: A PROSPECTIVE OBSERVATIONAL COHORT STUDY OF FETAL IMMUNE-MEDIATED HIGH-DEGREE HEART BLOCK

Few studies are specifically designed to address health concerns that are already relevant during pregnancy. The consequence is a lack of evidence on best clinical practice. This includes mothers and their babies when pregnancy is complicated by fetal heart block. To this day, physicians need to make decisions about the management of such pregnancies without evidence from prospective clinical trials. The SLOW HEART REGISTRY is a multi-centered prospective observational study that will address the knowledge gap to guide future management of high-degree immune-mediated heart block to the best of care. The study seeks to establish an international database of the management and outcome of affected fetuses, to be used to publish information on the results of currently available prenatal care and to evaluate the need for additional research.

Study Outline.

Sites. Study site participation requires site REB approval and an executed legal contract with the primary investigator/SickKids Hospital, Toronto (study sponsor). To obtain the SickKids REB-approved protocol and other relevant documents please contact: Slow.heart@sickkids.ca; edgar.jaeggi@sickkids.ca

Patients. Eligible for study enrollment are mothers with a new fetal diagnosis of suspected or confirmed immune-mediated 2nd or 3rd degree atrio-ventricular heart block (AVB) ≤ 32+0 prior to 32+0 gestational weeks. Excluded are mothers with seronegative heart block, fetal bradycardia diagnosis other than AVB, maternal-fetal conditions (other than cardiac NL) associated with high odds of premature delivery or death and contraindications to the prenatal use of steroids. Written informed maternal consent within maximally 8 days of diagnosis is required to participate.

Prenatal and Postnatal Management. All management decisions are made by the treating physicians in accordance with institutional standards. Data collection in REDCap is prospective and longitudinal.

Objectives. The primary objective will be to determine the rate of transplant-free survival to 1 year based on the primary management decision at the time of AVB diagnosis

- Cohort 1: Not treated with fluorinated glucocorticoids
- Cohort 2: Treated with fluorinated glucocorticoids

Secondary objectives will be to determine

- The evolution of key clinical findings to birth
- The changes in prenatal treatment (steroids; beta-mimetics; IVIG) to birth;
- Prevalence of relevant fetal-maternal events and complications;
- Gestational age and weight at birth;
- Postnatal management (pacing; steroids; IVIG); and the clinical evolution to 1-3 years of life (cardiac function; developmental milestones; growth; health).

Anticipated study duration. We expect to be able to enroll 50 AVB cases/year in this multicenter study and overall >100 cases in each study cohort (untreated; steroid treated). Eligible participants will be prospectively recruited over a 5-year period (to December 2025). Outcome data will be collected until the postnatal neurodevelopmental assessment by ASQ-3 has been completed (latest December 2027).

Funding. No funding is currently available for study sites planning to participate in SLOW HEART.