Ex-vivo heart perfusion system for pediatric heart transplantation
RESEARCH PROFILE

Background

Brief description of research study:

Objective #1: To assess the feasibility of the pediatric ex-vivo heart perfusion system. Feasibility will be confirmed by successful perfusion of a donated heart without device failure.

Objective #2: To assess the safety of the pediatric ex-vivo heart perfusion system in improving the function of marginal NDD/DNC hearts and reanimating DCD/DCC hearts. Safety will be measured by the ability to reanimate the heart through successful perfusion for ≥ two hours.

Up to 5 hearts in total will be tested.

Program: Division of Cardiovascular Surgery, The Hospital for Sick Children

Contact Person(s) & Contact Information:

Primary Contact: Dr Osami Honjo, cell: 647 967-6726, office 416) 813-7984

Secondary contact: Dr Juglans Alvarez, cell: 647 448 1644, office: 416 340 4800 Ext. 5133

Offering Information:

Hearts will be offered out (including for heart valves) and if declined for transplantation, TGLN will offer the heart to HSC [Dr Honjo] for research. HSC [Dr Honjo] will communicate the offer to the research team and respond to TGLN. HSC [Dr Honjo] will communicate recovery timing details to the research team.

Inclusion:

1. DCD/DCC & NDD/DNC donors, ≥ 38-weeks gestational age and < 30 years old
2. Donor is located within 60-90 min of GTA
3. Body weight ≥ 3.0 Kg and ≤ 70.0 kg
4. Absence of aortic insufficiency, such as:
   a. severe cardiac segmental wall abnormalities
   b. Absence of coronary artery diseases
   c. Absence of cardiac valve anomalies
5. Requires TGLN consent for Scientific Research from the donor next of kin / substitute decision-maker.

Exclusion:

No exclusions. Donors not given heparin will not be excluded.

Recovery

COVID CONSIDERATIONS

Transportation: TGLN and transplant programs have worked together to limit the number of people travelling in each vehicle to allow spacing and minimize risk. Therefore, the UHN cardiac retrieval team will be required to arrange their own transportation.

Personal Protective Equipment: UHN cardiac retrieval team will supply their own N95 masks where applicable.

Methods:

Blood

Recovery of blood will be done by the research team after determination of death and before giving cardioplegia solution.

The amount of blood recovered is ~ 40-50% of total blood volume. This is based on the weight and age of the donor (85-105 ml/kg in neonates, otherwise 75-80 mL/kg).

(1) For NDD/DNC cases, 40-50% of total blood volume may be recovered prior to cross-clamp in the OR.

(2) For DCD/DCC cases, 40-50% of total blood volume may be recovered pre-flush.

Heart

Recovery of the hearts will be done by the UHN cardiac retrieval team. Hearts will be procured as per standard procedure. The SRC(s) will bring the routine supplies required for heart recovery.

*Please note, only Baxter tubing to be used until further notice.

UHN cardiac/lung transplantation retrieval team will bring supplies specific to the ex vivo machine (bags, sterile transfusion line and puncture needle for collection of blood), as well as the heart transplant solution (20 mL/kg).

Requirements for Perfusion: Standard heart recovery
Time Requirements: Standard heart recovery
Impact on Transplant/ Recovery Procedure: None
Effect on Body / Post-Mortem Care: None
Consent Considerations: Requires consent for Scientific Research from the donor NOK
Recovery Personnel: Research Team
Credentialing: As per PRC database.
Required Documentation: As per usual documentation