A-NRP Donor Safety Study "CONCLUDE"
RESEARCH PROFILE

Confirming the permanent cessation of intracranial circulation during Abdominal Normothermic Regional Perfusion after the determination of death by circulatory criteria

Background:

Brief description of research study:

Abdominal Normothermic Regional Perfusion (A-NRP) is a new postmortem donor intervention technique that uses an ex vivo system to re-oxygenate and re-circulate blood throughout the donor abdominal compartment after death determination but prior to organ recovery. This intervention reverses ischemic injury that the organs sustain during the dying process and may improve the quality and quantality of available organs.

Prior to implementing A-NRP as standard of care in Ontario, TGLN is performing a multi-centre donor safety study at participating hospitals. The study will determine whether the A-NRP surgical methods and procedures outlined in the protocol are effective at maintaining the permanent cessation of donor intracranial circulation during A-NRP after Death Determination by Circulatory Criteria (DCC) (i.e. that they are effective at preventing resumption of intracranial circulation during resumption of regional circulation in the abdomen).

Recruitment target: 20-30 patients across 3 participating sites over 12 months

Contact Person(s) & Contact Information:

London Health Sciences Centre: University Hospital and Victoria Hospital
Availability: 24/7
*For all LHSC site staff, if there is an extension number, the phone number that precedes is **519-685-8500**. Contact via cell or pager as primary. Pager if urgent.*

Role	Name	Contact Numbers	Email
Research Coordinators/ Study Consent:	Crystal Engelage	Pager: 17472 Cell: 519-719-2273 Office: 37517	Crystal.Engelage@lhsc.on.ca
	Tracey Bentall (back-up UH)	Pager: 13323 Cell: 519-902-9512 Office: 32546	Traceyc.Bentall@lhsc.on.ca
	Eileen Campbell (back-up VH)	Pager: 15673 Office: 55664	Eileen.Campbell@lhsc.on.ca

University Health Network: Toronto Western Hospital
Availability: Monday to Friday, 8:00am to 8:00pm
SOTD can notify Research Coordinator of consented donors

Role	Name	Contact Numbers	Email
Research Coordinators/ Study Consent:	Erin Winter	Cell: 416-209-7535	Erin.Winter@uhn.ca
	Reggie Peralta (back-up)	Cell: 647-500-1649	Peregrina.Peralta@uhn.ca
	Briar Coman (back-up)	Cell: 416-702-8082	Briar.coman@uhn.ca

Offering Information:

After an abdominal organ has been accepted by UHN or LHSC, the SOTD will contact the Research Coordinator and notify them of a potential case for A-NRP CONCLUDE.

Donor inclusion criteria:

1. ≥ 18 years of age
2. Potential adult DCC donors whose families/surrogate decision makers have consented to DCC organ donation according to current criteria of the participating transplant programs.
    - DCC donors may include patients donating a liver, kidneys, pancreas, and/or lungs
3. Abdominal organ accepted for transplant
4. Must be located at a participating hospital:
    - LHSC: University Hospital, Victoria Hospital
    - UHN: Toronto Western Hospital

Donor exclusion criteria:

1. < 18 years of age
2. DCC donors who proceed to donation following medical assistance in dying or those who are able to provide first-person consent at the time of donation
3. Registered Consent Decision of Transplant only
4. Injuries that anatomically preclude the use of neurological monitoring

Recovery

Covid Considerations: Personal Protective Equipment: TWH and LHSC will supply their own N95 masks where applicable.

Method: After determination of death by circulatory criteria has occurred, an A-NRP case will be initiated in accordance with the protocol.

Logistics:

- OR will be booked by SOTD using usual process, and consult with Research Coordinator
- Neuromonitoring equipment will be brought to the bedside/OR by the neuromonitoring study team
- Perfusion circuit (Cardiohelp System), tubing, priming solutions and surgical equipment will be brought to the OR by LHSC's TDS, or by TWH's Perfusion Services Team

Supplies to be provided by TGLN SRC: None

Requirements for Perfusion:
As per perfusionist's preference

Time Requirements:
Preference to book OR during the daytime (10am onwards). Procedure expected to be performed within 2-2.5 hours.

Impact on Transplant/ Recovery Procedure:

The neuromonitoring team will continuously monitor the donor for resumption of brain blood flow and/or activity. In the event of any evidence of brain blood flow or activity, or an unresolvable failure of the neuromonitoring equipment, the neurocritical care expert assigned to monitoring will instruct the A-NRP team to abort all normothermic regional perfusion immediately, wait for brain activity and/or circulation to stop*, then start standard rapid recovery process.

Should A-NRP be stopped in the context of the protocol for any reason, the surgical teams will proceed with conventional rapid recovery of abdominal organs, and/or lungs.

The surgical teams should be onsite and available for the duration of A-NRP.

*There is no need for 5 min observation period as circulation is provided by A-NRP ECMO pump, so once the pump is stopped the cessation of circulation is permanent.
Effect on Body / Post-Mortem Care: Usual procedure
Consent Considerations:
- Requires consent for research from the donor NOK obtained by the SOTD - Requires consent for A-NRP Research Study CONCLUDE by Research Coordinator / Study Team
Recovery Personnel:
UHN abdominal recovery team, UHN lung thoracic recovery team, LHSC abdominal recovery teams, LHSC Transplant Donor Specialist (TDS). For A-NRP kidney-only donors at TWH, the UHN surgical recovery team will perform the recoveries.
Credentialing: As per PRC database.
Required Documentation:
Usual documentation, and surgeon to add comment in DCD Retrieval Operative Note(s), and SRC to add note in Organ Donor Surgery Information (ODSI) form.
Transportation: N/A