Monitoring Organ donors to Improve Transplantation Results

www.monitorstudy.org

Grant #R38OT10587
A grass-roots effort

Table F1. MOnIToR Planning and Executive Committees

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
<th>PC</th>
<th>EC</th>
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<tbody>
<tr>
<td>Ali Al-Khafaji, MD</td>
<td>University of Pittsburgh</td>
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<td>Luis Angel, MD</td>
<td>University of Texas</td>
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<td>Michelle Berens, RN</td>
<td>Gift of Hope, Elmhurst, IL</td>
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<td>Christine Cottingham, RN, MS</td>
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<td>Michele Elder, RN</td>
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<td>Mike Harmon, RN</td>
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<td>J. Steven Hata, MD</td>
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<td>Ibtesam Hilmi, MD</td>
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<td>John A. Kellum, MD</td>
<td>University of Pittsburgh</td>
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<td>Dan Lebovitz, MD</td>
<td>Cleveland Clinic/LifeBanc</td>
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<td>Ken McCurry, MD</td>
<td>University of Pittsburgh</td>
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<td>Martin Mozes, MD</td>
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<td>Raghavan Murugan, MD</td>
<td>University of Pittsburgh</td>
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<td>C. Lee Parmley, MD, JD</td>
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<td>Ali Salim, MD</td>
<td>Cedars-Sinai Hospital</td>
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<td>Alan Spriggs</td>
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<td>Mike Souter, MD</td>
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<td>Susan Stuart RN, MPM</td>
<td>CORE, Pittsburgh, PA</td>
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<td>Ken Wood, MD</td>
<td>University of Wisconsin</td>
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PC – Protocol Planning Committee; EC – Executive Committee
Purpose

“To increase the number of organs transplanted per donor using protocol-guided donor fluid management strategy after brain death”

Goals of management is to optimize:
- Intravascular volume status
- Blood pressure
- Cardiac output
- Oxygen delivery to transplantable organs
- (Evaluate inflammatory biomarkers in brain dead donors)
Outcomes

■ Primary
  ■ Mean number of organs transplanted per donor

■ Secondary
  ■ 6 month hospital-free survival in recipients
  ■ Mean number organs transplantable
  ■ Changes in inflammatory markers (IL-6)

Monitoring Organ donors to Improve Transplantation Results
Enroll 960 Brain Dead Donors over 18 months period

80% statistical power to detect a 0.5 organ/donor increase (16% increase)

Randomized 1:1 protocol arm versus usual care (by site and age).
- Randomization done via secure website.
- Goal of involving as many OPOs as possible to expedite data collection.
- Currently 6 OPOs are enrolling
Inclusion/Exclusion Criteria

**Inclusion Criteria**
- Declared brain dead
- Suitable for donation
- Standard & extended criteria apply

**Exclusion Criteria**
- <16 years
- Pregnant donor
- Inability to perform LiDCO monitoring
- Immunosuppressive Rx
Resuscitation Algorithm

Monitoring Organ donors to Improve Transplantation Results
LiDCO Plus Monitor

Target values:
- MAP 60-70 mmHg
- CI ≥ 2.2
- PPV ≤ 13%

NO CONTROL OF ANY OTHER INTERVENTIONS SUCH AS HORMONAL REPLACEMENT, STEROIDS etc....
Usual Care Management

- Will follow site standard of care
- LiDCO not connected-not used
- Donor will be randomized
  - Cannot add donor if LiDCO not available
Why LiDCOplus?

- Calibrated system
  - Lithium dilution indicator

- Non-calibrated systems based on algorithms – not validated in brain death
  - 15% of cardiac output to cerebral circulation
  - 20% of oxygen consumption is the brain

- Support of company
  - Training
  - Troubleshooting
  - Equipment

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Blood Sampling

- Collection time
  - After randomization
  - Prior to explanation—Before donor is transferred to the OR.

- Bulk shipping of specimens to DCC.
  - Quarterly return to center
  - IL-6

Monitoring Organ donors to Improve Transplantation Results
Participating Organizations

LIFECENTER NORTHWEST
Serving Washington, Montana, Alaska, and North Idaho
Executive Committee

- Dan Lebovitz, MD
- Mike Souter, MD
- Susan Stuart, RN
- Shri Bharadwaj, MPH, MBA
- Clifford Parmley, MD
- Ladora Dils
- John Kellum, MD
- Ali Al-Khafaji, MD, MPH

LifeBanc
LifeCenter Northwest
CORE
LifeLink of Georgia
Tennessee Donor Services
LifeLine of Ohio
University of Pittsburgh
University of Pittsburgh

Monitoring Organ donors to Improve Transplantation Results
Advisory Committee

Rupert Pearse MD, Chair
Senior Lecturer & Consultant in Intensive Care Medicine
Queen Mary’s University of London, UK

Luis Angel, MD, Committee member
University of Texas

Howard Rockette, PhD, (Independent statistician)
Professor of Biostatistics
University of Pittsburgh

Monitoring Organ donors to Improve Transplantation Results
Enrollment

Observed, Expected, and Projected Enrollment

Monitoring Organ donors to Improve Transplantation Results
Advantages of Participating

- Ensure the success of the OPO community's first multi-center RCT
- Membership in a research collaboration with a proven track record
- Early adoption of a therapy that will increase organ recovery

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