Study Protocol

Naloxone for Optimizing Hypoxemia of Lung Donors (NO-HOLDS)

NCT02581111

Date: August 14, 2015

Project Goals

1. Evaluate whether naloxone can improve oxygenation / reverse hypoxemia in lung-eligible brain-dead (BD) organ donors
2. Demonstrate feasibility of prospective multi-OPO clinical trials as part of the ODRC

Study Population (determined at initiation of OPO management)

1. Lung-eligible BD donors (age 13-70, no established severe lung disease – e.g. COPD)
2. Arterial hypoxemia (P:F ratio < 300 on first ABG after initial OPO stabilization)

Study Protocol

1. All OPO-specific donor protocols (incl. lung optimization) should be followed
    a. Does not require any other change to practice or donor management
2. Randomization occurs for eligible donors after initial ABG (stratified by center)
3. Naloxone 8 mg IV (or saline) given once
    a. Co-administered with a neuromuscular blocking agent (NMB)
    b. Blinding of drug vs. placebo done at each OPO with sequential unmarked syringes (prefilled with naloxone or saline and numbered with central code)

Outcome Measures

1. Change in P:F ratio to final ABG – ABG obtained on 100% FiO2, PEEP 5
2. Change in P:F ratio to early ABG
3. Lungs recovered / transplanted (if not – reason, e.g. hypoxemia vs. COPD, other RO)

SRTR variables for O:E calculation (incl. age, race, ABO, smoker)

- Most of this could be abstracted post-hoc from OPO database
- Only study registration (with UNOS & OPO ID) entered into study-specific on-line database with syringe # and ABG PO_2 values (redcap.wustl.edu)