P-ICECAP

Pediatric Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients

Enrollment: goal 900 subjects, 5 years
Funding: NIH

Objectives

To characterize the duration response curve for hypothermia and determine:

1: whether the duration-response demonstrates cooling efficacy verses no cooling

2: the shortest duration of cooling that provides the optimal treatment effect (based on standardized neurobehavioral function test score and mortality one year later)

Study Summary

A multicenter, randomized, adaptive allocation clinical trial to identify the optimal duration of induced hypothermia for neuroprotection in comatose survivors of out-of-hospital cardiac arrest.

Inclusion Criteria

- 2 days to <18 years (at least 38 weeks corrected gestational age)
- Chest compressions >2 min and ≤60 minutes
- Coma or encephalopathy after resuscitation from OHCA
- Mechanically ventilated via ETT or trach
- Definitive temperature control device already initiated
- Ability to randomize within 6 hours of ROSC*
- Intent to maintain life support for 120 hours

*ROSC: First ROSC sustained for 20 minutes

Exclusion Criteria

- LAR does not speak English or Spanish
- Severe hemodynamic instability with epi/norepi of 2ug/kg/min or ECMO
- Pre-existing neuro deficits AEB PCPC of 5 or progressive degenerative encephalopathy
- Pre-existing terminal illness unlikely to survive 1 year
- CA with brain, thoracic or abdominal trauma
- Active and refractory severe bleeding prior to randomization
- Extensive burns or skin lesions
- Sickle cell anemia
- Pre-existing cryoglobulinemia
- Non-fatal drowning in ice covered water
- CNS tumor with ongoing chemotherapy
- Previous enrollment
- Prisoner
- Chronic hypothermia
- Pregnancy (neg test to enroll)
- New post cardiac arrest DI

Intervention:

Randomization to duration of Cooling to 33C: 0, 12, 18, 24, 36, 48, 60, 72, 84, 96 hours followed by rewarming.
Total temp control for 120 hours

Primary Outcome:

- Composite Vineland-3 Mortality Score at 1 year