

Pediatric Influence of Cooling Duration on Efficacy in Cardiac Arrest Patients (P-ICECAP)

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 2 days to 17 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion criteria:

- Age 2 days to < 18 years with corrected gestational age of at least 38 weeks
- Chest compressions for at least 2 minutes
- Coma or encephalopathy after resuscitation from Out-of-Hospital Cardiac Arrest (OHCA)
- Requires continuous mechanical ventilation through endotracheal tube or tracheostomy
- Definitive temperature control device initiated
- Randomization within 6 hours of Return of Spontaneous Circulation (ROSC)
- Informed consent from Legally Authorized Representative (LAR) including intent to maintain life support for 120 hours

Exclusion criteria:

- Glasgow Coma Motor Score (GCMS) = 6
- LAR does not speak English or Spanish
- Duration of Cardiopulmonary Resuscitation (CPR) > 60 minutes
- Severe hemodynamic instability with continuous infusion of epinephrine or norepinephrine of 2 micrograms per kilogram per minute ($\mu\text{g/kg/minute}$) or initiation of Extracorporeal membrane oxygenation (ECMO)
- Pre-existing severe neurodevelopmental deficits with Pediatric Cerebral Performance Category (PCPC) =5 or progressive degenerative encephalopathy
- Pre-existing terminal illness, unlikely to survive to one year
- Cardiac arrest associated with brain, thoracic, or abdominal trauma
- Active and refractory severe bleeding prior to randomization
- Extensive burns or skin lesions incompatible with surface cooling
- Planned early withdrawal of life support before 120 hours
- Sickle cell anemia
- Pre-existing cryoglobulinemia
- Non-fatal drowning in ice covered water
- Central nervous system tumor with ongoing chemotherapy
- Previous enrollment in P-ICECAP trial
- Prisoner
- Chronic hypothermia
- New post-cardiac arrest diabetes insipidus
- Pregnancy

Conditions & Interventions

Interventions:

DEVICE: Therapeutic Hypothermia

Conditions:

Cardiac Arrest, Out-Of-Hospital, Hypothermia, Induced, Hypoxia-Ischemia, Brain

Keywords:

Bayesian Adaptive Clinical Trial, Hypothermia, therapeutic, Coma, Pediatric

More Information

Description:

This is a multicenter trial to establish the efficacy of cooling and the optimal duration of induced hypothermia for neuroprotection in pediatric comatose survivors of cardiac arrest. The study team hypothesizes that longer durations of cooling may improve either the proportion of children that attain a good neurobehavioral recovery or may result in better recovery among the proportion already categorized as having a good outcome.

Contact(s): Abigail Gibson - abigail.gibson@cchmc.org

Principal Investigator:

Principal Investigator ID:

Phase: NA

IRB Number:

System ID: NCT05376267

