



Pager 970-1425

Preemie Hypothermia

Need to consent/randomize within 6 hours

If you definitely want to cool the infant, they should not be enrolled in this study. This is a randomized trial. Half of the infants will be cooled and half will only be monitored.

Inclusion Criteria

Infants 33 0/7 to 35 6/7 weeks GA (best obstetrical estimate) and **≥1500 grams birth weight** (to minimize potential difficulties placing esophageal probe) who meet clinical, biochemical and neurologic criteria for moderate to severe NE in this GA range at ≤6 hours age:

As potential eligibility for randomization, infants must first meet the inclusion criteria in either Step 1 or 2:

Step 1

If BLOOD GAS IS AVAILABLE:
(cord or drawn < 60 minutes of age)

Cord pH or any postnatal blood gas pH ≤ 7.0

OR

Cord Base Deficit or any postnatal blood gas Base Deficit ≥16 mEq/L

If criteria in either Step 1 are met, skip Step 2 and continue eligibility assessment for presence of exclusion criteria. If criteria for Step 1 are not met, move on to Step 2.

Step 2

If BLOOD GAS IS NOT AVAILABLE, OR pH 7.01 -- 7.15, or Base Deficit 10 -- 15.9mEq/L

You need to have both:

Acute perinatal event (abruption placenta, cord prolapse, severe FHR abnormality: variable or late decelerations)

AND

An Apgar score ≤ 5 at 10 minutes or Continued need for ventilation initiated at birth and continued for at least 10 minutes

Exclusion Criteria

- 1) Receipt of paralytic agent or sufficient sedative or analgesic agent that is considered by the examiner to confound the qualifying neurologic exam
- 2) Etiology of NE not likely to be hypoxic-ischemic in origin
- 3) Major congenital anomaly that may confound outcome
- 4) Considered to be moribund and will not be receiving full intensive care
- 5) Equipment and/or appropriate staff not available
- 6) Infant was cooled prior to arrival at the NRN center and had a core temperature < 1hr of age) have a pH > 7.15 AND a base deficit < 10mEq/L
- 7) Unable to randomize infant by 6 hours of age
- 8) Infant needs ECMO
- 9) **All blood gases (cord and postnatal at < 1hr of age) have a pH > 7.15 AND a base deficit < 10mEq/L**

If the infant meets these criteria, please page research (970-1425) and we will make sure you have a certified examiner to assist with the neuro exam portion.

Darbepoetin

Need to consent within 24 hours

Inclusion Criteria

• 23 0/7-28 6/7 weeks gestation

• < 24 hours postnatal age

Exclusion Criteria

- **Hematocrit > 60%**

- Infants with known congenital or chromosomal anomalies, including congenital heart disease and known brain anomalies
- Hemorrhagic or hemolytic disease
- EEG confirmed seizures
- Congenital thrombotic disease
- Systolic blood pressures >100 mm Hg while not on pressor support
- Receiving Epo or Darbe clinically, or planning to receive Epo or Darbe during hospitalization
 - Infants in whom no aggressive therapy is planned
- Family will NOT be available for follow-up at 22-26 months
- Infant unlikely to survive • Infant enrolled in a conflicting trial

We would appreciate a page about these potentials on weekends and holidays.

HIP Trial

Let the research team know if you are aware of a child with a hernia. No need to page. Just if you see us in the hall or email.