Do Antenatal Steroids Affect Maturation of the Amplitude Integrated Electroencephalogram in Late Preterm Infants? A Secondary Study by the NRN for the MFMU ALPS Trial

OBJECTIVE: To assess, whether ante-natal administration of corticosteroids to mothers of 34^0 – 35^6 weeks gestation is associated with an aEEG pattern consistent with increased maturity as demonstrated by more periods of quiet sleep compared to administration of placebo.

ORGANIZATION

Clinical centers: University of Alabama, Brown University, Case Western Reserve University, Duke University-University of North Carolina at Chapel Hill, Nationwide Children's Hospital (Ohio State University), Stanford University, University of Texas (Houston and Southwestern)

Subcommittee: Abbot Laptook MD, Lina Chalak MD, Ross Sommers MD, Athina Pappas MD, Alexis Davis MD, Pablo Sanchez MD, Seetha Shankaran MD, Krisa Van Meurs MD, William Oh MD, Dwight Rouse MD, Angelita Hensman RN, Christine Fortney RN, Abhik Das PhD, Rose Higgins MD

Data Center RTI International

DESIGN

Type:
- Observational secondary study to the MFMU ALPS randomized trial: http://www.bsc.gwu.edu/mfmu/projects/brieftrl.cgi#ALPS

Major inclusion criteria:
- Mothers enrolled in the ALPS trial
- Gestational age limited to 34^0 to 35^6 weeks

Major Exclusion Criteria

ALPS trial exclusion criteria

Neonatal exclusions (separate from ALPS)
- Seizures
- Hypoxia-ischemia
- Inability to obtain informed consent
- Inability to perform the initial aEEG recording within 72 hours after birth

Enrollment Goal: 99 infants

SCHEDULED EVALUATIONS

Data will be collected on:
- Eligibility, Enrollment and Consent Status
- Baseline Characteristics
- Clinical Surveillance/Outcome
- aEEG Evaluation
- Safety Information

OUTCOME MEASURES

Primary outcome:
- Frequency of quiet sleep intervals (number/hour) in an aEEG recorded at less than 72 hours of age.

Secondary outcomes:

First aEEG
- Span width voltage between quiet sleep intervals
- Lower border voltage between quiet sleep intervals
- Percent discontinuity
- Characterization of quiet sleep intervals (percent mature, immature, interrupted)
- Duration of quiet sleep intervals

Second aEEG
- Interval changes between 1st and 2nd aEEG

Time of resolution of clinical morbidities within each treatment group

TIMETABLE

06/2012 through 06/2013

CONCLUSIONS

Study ongoing