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 34⁰ to 35⁶ 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](http://www.bsc.gwu.edu/mfmu/projects/brieftrl.cgi#ALPS)

**Major inclusion criteria:**
- Mothers enrolled in the ALPS trial
- Gestational age limited to 34⁰ to 35⁶ 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