

## NICHD Neonatal Research Network

### DELIVERY ROOM CONTINUOUS POSITIVE AIRWAY PRESSURE/POSITIVE END EXPIRATORY PRESSURE (CPAP/PEEP) IN EXTREMELY LOW BIRTH WEIGHT (ELBW) INFANTS

**OBJECTIVE** A feasibility trial to determine whether the randomized use of Positive end-expiratory pressure (PEEP) and/or continuous positive airway pressure (CPAP) can be performed in the DR followed with universal NICU CPAP and intubation according to criteria within the protocol.

#### ORGANIZATION

Clinical centers: Network: Case Western Reserve, University of Alabama, University of Cincinnati, University of Miami, University of California at San Diego

Subcommittee: Neil Finer MD, Avroy Fanaroff MD, Edward Donovan MD, Waldemar Carlo MD, Shanaz Duara MD

#### DESIGN

Type: 

- Prospective, randomized, multi-center pilot feasibility trial

Major inclusion criteria: 

- Inborn Infants
- Infants with a gestational age of 27 6/7 weeks or less
- Infants who will receive full resuscitation as necessary

Treatment groups: Treatment infants will receive 100% oxygen and CPAP or positive pressure ventilation with PEEP (if the infant requires positive pressure ventilation, PPV) until admission to the NICU

Control infants will be treated with 100% oxygen and no CPAP and, if the infant requires bag and mask PPV, no PEEP will be utilized until admission to the NICU.

Level of masking: 

- Unmasked

Randomization: Clinical center by week.

Sample size: 

- Goal = 100
- Based on estimating the feasibility rate with a 95% confidence interval of  $\pm 10\%$ .

#### SCHEDULED EVALUATIONS

Pre-randomization: 

- Eligibility

Post-randomization: 

- Maintained on CPAP upon admission to the NICU using the methodology utilized in the unit
- Use of specified criteria for intubation during the first 7 days after delivery

#### MANAGEMENT PROTOCOLS

DRCPAP: 

- CPAP or PPV administered via NeoPuff®

Management: 

- Video recording to monitor protocol adherence

#### OUTCOME MEASURES -

Primary: 

- Compliance with the study protocol

Secondary: 

- Time to improvement in oxygen saturation
- Duration of PPV for resuscitation in the delivery
- Five minute Apgar
- Total duration of mechanical ventilation during NICU
- Proportion of infants requiring surfactant
- Incidence of air leaks on admission and overall
- Incidence of CLD at 36 weeks (using physiologic definition of BPD)

#### TIMETABLE

Randomization: 

- 7/2002–7/2003

#### CONCLUSIONS

Enrollment began 7/8/2002

#### DATA CENTER

RTI, International