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 + 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
DRCAP
- CPAP or PPV administered via NeoPuff®
Management:
- Video recording to monitor protocol adherence

OUTCOME MEASURES -
Primary:
- Compliance with the study protocol
- 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)

Secondary:

TIMETABLE
Randomization:

CONCLUSIONS
Enrollment began 7/8/2002

DATA CENTER
RTI, International

7/26/02