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## For immediate release

### **International Trial Shows Cool-Cap Discovery May Reduce Brain Injury in Newborns**

**September 16, 2004—Seattle, WA**—An international clinical trial in which 28 hospitals participated has shown that a head-cooling device may reduce brain damage in oxygen-deprived newborn babies.

The results of the Cool-Cap trial — performed on 234 infants between July 1999 and September 2003 in the United States, Canada, New Zealand and the United Kingdom — were presented to the international pediatric and neonatal community at the annual meeting of the Society for Pediatric Research in San Francisco, Calif., in May 2004. The findings have been submitted by the investigators for publication in a peer-reviewed journal and, by the manufacturer, for review by the FDA.

This trial has shown that a head-cooling device applied soon after birth may reduce brain damage in some oxygen-deprived newborn babies when compared with babies who received standard medical care. The device was developed from research conducted by members of the investigating team. Pilot studies led by the late Professor Tania Gunn (Auckland) had suggested the safety of the approach. Olympic Medical, of Seattle, Wash., manufactured the device and supported the costs of the Cool-Cap trial. The trial was designed and analyzed independent of the company by an international scientific advisory board of academic clinicians, listed below, who provided scientific leadership for the trial. The trial was reviewed by an independent safety monitoring committee.

The Cool-Cap investigational trial was registered with the United States Food and Drug Administration. Infants assigned to the hypothermia group were fitted with the Cool-Cap for 72 hours and body temperatures were tightly controlled and maintained between 34°C and 35°C (i.e., between 93°F and 95°F) to reduce the chance of side effects. Babies in the control group received standard clinical care for their institution. At 18 months, infants received formal neurological and developmental assessment, as well as testing of their hearing by staff who were not aware of whether or not the infant had received cooling treatment.

The key findings of the trial were that:

- Not every baby could respond to the therapy.
- Brain wave analysis used soon after birth enabled the researchers to divide the patients into two groups. One group with less severe brain wave changes had the best chance of responding to treatment. This group represented about 80% of the babies in the study. In this group there was a clinically and statistically significant reduction in the combined rate of death and severe disability (defined by motor abnormality, developmental score and cortical blindness) at 18 months of age, compared with babies who received standard medical care.
- In babies with more severe brain wave changes, treatment with the Cool-Cap showed no apparent benefit.
- Cooling therapy as administered in this trial, with precise control of body temperature and maintenance of full intensive support, was not associated with significant side effects.

## **Notes**

The researchers pay tribute to the willingness of the families who participated in this important trial.

The international trial was sponsored by Olympic Medical Corporation (based in Seattle, Wash., USA). The company is seeking FDA approval to market the device.

In developed countries, about 1–2 in 1,000 newborn babies are at risk of brain damage during the birth process. Those who survive can be left with heartbreaking conditions such as cerebral palsy or severe intellectual impairment.

The Cool-Cap trial results were the culmination of several years of basic and clinical research in many laboratories, and provide the first evidence in humans that brain damage at birth may respond to treatment in suitable individuals. While more research is needed, the findings offer hope that over time it may help many thousands of babies around the world who are affected by problems at birth.

Other clinical trials of cooling in newborn babies are continuing around the world. As the first study of this type, the results are important and promising. However the investigators point out that there is ample evidence that uncontrolled cooling and rewarming in the newborn carries many potential risks. At this time the investigators recommend that any use of hypothermia treatment in newborn infants should only be in approved clinical trials with rigorous monitoring and clinical supervision. It is also important to note that hypothermia has been tested only in term infants and it is not known whether cooling may be helpful or harmful in premature infants. Until hypothermia treatment in the newborn has received formal regulatory approval, it would be unethical to apply any form of this therapy except in a properly supervised clinical trial.

## **Clinical Trial Participants**

**Executive Committee:** P.D. Gluckman (chair), J.S. Wyatt, A.J. Gunn (scientific officer)

**Scientific Advisory Committee:** J.S. Wyatt (chair), R. Ballard, A.D. Edwards, D.M. Ferriero, P.D. Gluckman, A.J. Gunn, R. Polin, C. Robertson, A. Whitelaw

**Data Safety Committee:** R. Soll (chair), M. Bracken, C. Palmer, M. Heymann, A. Wilkinson

**Hospital Investigators:** J. Kaiser, M. Battin, J. Khan, T. Raju, R. Polin, R. Sahni, U. Sanocka, A. Rosenberg, J. Paisley, R. Goldberg, M. Cotten, A. Peliowski, E. Phillipos, D. Azzopardi, A.D. Edwards, F. Northington, J. Barks, S. Donn, B. Couser, D. Durand, K. Sekar, D. Davis, M. Blayney, S. Adeniyi-Jones, T. Yanowitz, R. Guillet, N. Laroia, N. Finer, F. Mannino, J. Partridge, D. Davidson, A. Whitelaw, M. Thoresen, J.S. Wyatt, F. O'Brien, B. Walsh, J. Perciaccante, M. O'Shea

**Manufacturer's Representatives – Olympic Medical:** J. Jones, T. Weiler, J. Mullane, D. Hammond

**Hospitals Involved – Clinical Sites:** Arkansas Children's Hospital; National Women's Hospital, NZ; Children's Memorial Hospital, Chicago; Prentice Women's Hospital of Northwestern Memorial Hospital; University of Illinois at Chicago Medical Center; Children's Hospital of New York – Presbyterian; Children's Hospital of Denver; Duke University Medical Center; Royal Alexandra Hospital / University of Alberta Hospital; Hammersmith Hospital, UK; Johns Hopkins University; University of Michigan Medical Center – Mott Children's Hospital; Children's Hospital and Clinics of Minneapolis; Children's Hospital and Research Center at Oakland; Children's Hospital of Oklahoma; Children's Hospital of Eastern Ontario / The Ottawa Hospital; AI Dupont Children's Hospital at Thomas Jefferson University Medical Center; Magee Women's Hospital / Children's Hospital of Pittsburgh; Golisano Children's Hospital at Strong; University of California, San Diego Medical Center; University of California, San Francisco Children's Hospital; Schneider Children's Hospital; Southmead Hospital and St. Michael's Hospital, Bristol, UK; University College Hospital, London; Vanderbilt Children's Hospital; Wake Forest University Baptist Medical Center