



Heat Loss Prevention Trial Newsletter #5

Our next HeLP Trial Investigators' Meeting takes place at the Pediatric Academic Societies' General Meeting in San Francisco on Monday May 1st 2006 at 7:30am. Breakfast will be served. Everyone is welcome!

Welcome to our fifth HeLP Trial Newsletter. The purpose of the newsletter is as always, to keep you up to date on trial-related information and share with you the great work our HeLP Trial participating centers are doing.

Institutional Consent

For those interested, the documents necessary for an IRB/HREB application for Institutional Consent have been sent via email to all of our HeLP Trial participating centers. All documents are also available on the VON website (www.vtoxford.org).

Please, let us know if you have made the decision to pursue institutional consent so we can help you through the process. If you have any further questions, please contact Luba Slatkovska.

Follow-Up

As part of our trial, we are evaluating survival and developmental outcome at 18 to 24 months corrected age. The first infants enrolled in the HeLP Trial are now reaching the 18 months mark!

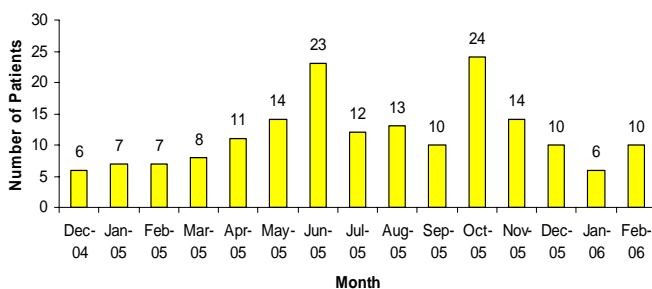
With respect to follow-up:

- 1) We ask that all centers fill out the Parental Interview and Reporting Questionnaire (PIRQ) on all enrolled infants who are alive at 18-24 months corrected age.
- 2) We ask that centers that have a follow-up clinic fill out our Extended Follow Up (EFU) forms in addition to the PIRQ.

Before the follow-up documents are used to collect data, each participating center must inform their local IRB that we are entering this phase of the study, and supply them with copies of data forms. Therefore we will be emailing the PIRQ to all participating centers, and the EFU to centers with follow-up clinics. A sample letter to IRB will be included with the manual of operations for both the PIRQ and EFU.

Because the PIRQ data forms are scanned into a database, they must be filled out on official data booklet, which will be mailed to each participating center.

HeLP: Monthly Patient Enrollment



Randomization

We are happy to announce that we now have **187 infants enrolled at 33 centers**, with 8 infants in the <24 weeks strata. Since January 2006, 4 new sites have joined the trial. Welcome! We are still **actively recruiting new sites**; so if you know of an interested VON center, please contact Luba Slatkovska.

Announcements

The next investigator meeting is taking place on Monday May 1st 2006 at the Pediatric Academic Societies' General Meeting in San Francisco. The meeting starts at 7:30 and is being held at the Argent Hotel in the Private Dining Room in Jester's Restaurant. Breakfast will be provided. We will be discussing institutional consent and follow up. Hope to see you there!

For map of Argent Hotel location please refer to:

<http://www.pas-meeting.org/2006SanFran/Travel/HotelMap.pdf>

Reminders

Please remember to fax us (416 323 6011) your annual IRB/HREB approval letter as soon as you receive it. Without an official and up-to-date approval letter on our file, data from enrolled infants cannot be entered into our data base.

FAQ

Q: The AAP/NRP guidelines for Neonatal Resuscitation state: "Polyethylene bags may help maintain body temperature during resuscitation of VLBW infants." If the AAP/NRP recommends the use of the bags, can we continue the study?

A: As stated in these guidelines, we are reasonably confident that wrapping reduces heat loss in VLBW infants. However, we do not yet know the long-term significance of this intervention. AAP/NRP guidelines acknowledge that long-term ramifications are unknown, since they do not indicate whether or not improved maintenance of body temperature through wrapping influences health outcomes. In this regard, the HeLP Trial examines the effects of wrapping premature newborns on morbidity and mortality. Until the results of this trial are known, we think equipoise exists with regards to wrapping premature newborns immediately after delivery and are not yet ready to recommend this practice to be included as part of standard of care.

Tips from Participating Centers

To calculate 36 weeks and 18 months adjusted age try the Adjusted Age Calculator (under Study Materials):

<http://www.vtoxford.org/home.aspx?p=research/help/index.htm>

Similarly, to determine the number of days at discharge try the Date Duration Calculator (check off the "Include end date" box):

<http://www.timeanddate.com/date/duration.html>

HeLP Trial Contacts:

Principal Investigators:

Maureen Reilly: maureen.reilly@sw.ca

Sunita Vohra: svohra@ualberta.ca

VON:

Karla Ferrelli: karla@vtoxford.org

Fax: 802 865 9613

Trial Coordinator:

Luba Slatkovska: lubomira.slatkovska@sw.ca

Tel: 416 323 6400 x3033; Fax: 416-323-6011