



## Heat Loss Prevention Trial Newsletter # 14

Thank you to all who attended the HeLP Trial Investigator's Meeting at the VON Annual General Meeting (AGM) on December 6<sup>th</sup> 2008 in Washington DC. If you are going to PAS in Baltimore and would like to have breakfast or lunch with Maureen, please contact Valeria at [helptrials@sunnybrook.ca](mailto:helptrials@sunnybrook.ca)

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

Thanks very much everyone and keep up the hard work.

### Investigators' Meeting 2008

The HeLP trial investigators' meeting was held on December 6<sup>th</sup> 2008 in Washington DC during the VON Annual Meeting. It was a great opportunity to see each other, share experiences between the HeLP centers and discuss different issues. We want to thank all our HeLP trial centers for their wonderful work, enthusiasm and commitment to the study.

Maureen has already sent out minutes and action points from the meeting along with an updated trial protocol. There have been some minor changes made which are outlined in the minutes from the investigator meeting. The protocol as well as an updated Manual of Operations can be found on the VON website. Your REB/IRB may need to be informed of the changes.

### News on Reimbursement

Some time ago we shared some wonderful news with you about our ability to offset some of the administrative costs you have incurred from participating in the trial. To review, we are providing a \$2000 administrative honorarium to each site with IC. This funding is available retroactively for sites that have already obtained IC and who have continued to enroll infants after September 1<sup>st</sup> 2007. This funding is also available for centers that are successful in obtaining IC for their center in the future. As well, starting September 1<sup>st</sup> 2007, a \$50 administrative fee is provided for each complete dataset (i.e. per enrolled subject enrolled after September 1<sup>st</sup> 2007).

We are currently finalizing the first set of payments. The first payment will be the IC administrative honorarium as well as the administrative fee for infants enrolled from September 1<sup>st</sup> 2007 to December 31<sup>st</sup> 2008. If your center has not provided us details regarding payment information for your center PLEASE DO SO IMMEDIATELY or you will not receive your money. Please submit this data to Valeria at [helptrials@sunnybrook.ca](mailto:helptrials@sunnybrook.ca) as soon as possible. Specifically we need to know to whom to make the check out to and where to mail the check.

### Consent Update - Important Changes

Recently we asked all our centers to fax us their consent forms. After reviewing them we have a couple of suggestions/changes that need to be made. Namely in most consent forms it is mentioned that the data would be analyzed at Edmonton University; that needs to be changed to Sunnybrook Health Sciences Centre (SHSC), University of Toronto since our new statistician Dr. Alex Kiss is affiliated with SHSC.

Most of the centers mentioned 18 months corrected age follow-up; however it wasn't very clear/obvious. To rectify this we suggest the addition of a paragraph explaining the planned follow-up process.

Example: Paragraph **Follow-up Assessment** – To help us answer other study questions we will also be collecting information about your baby's development. This information is gathered when your baby reaches 18 months corrected age. At this time a member of the study team will contact you by telephone and ask you some simple questions about your baby's development. This phone call will only take about 10 to 20 minutes. IF YOUR CENTER IS PARTICIPATING IN THE EXTENDED FOLLOW UP, YOU WILL ALSO NEED TO INCLUDE INFORMATION ABOUT THIS VISIT AND THE DATA THAT WILL BE TRANSCRIBED FOR THE HELP TRIAL.

Please consider making these changes, if necessary, on your consent forms. If you have more questions, please contact Maureen or Valeria.

### Site visit – Aultman Health Foundation

In February I (Maureen) was lucky enough to make my second site visit and was welcomed by the HeLP Trial staff at Aultman Hospital in Canton Ohio. Altman Hospital has been a member of the HeLP trial since its inception and is led by a wonderful team including Diana Hannay and Brenda Douglass. I hosted a lunchtime chat with the nursery staff and a dinner session for the nurses that included an update on the trial and a more in depth discussion regarding the practicalities of enrolling and wrapping infants in the trial. Continuing education credits

VON HeLP Trial website: <http://www.vtoxford.org/home.aspx?p=research/help/index.htm> (login: help trial; password: \*babywrap8\*)

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were available for nurses who attended the dinner session.

It was a great opportunity for me to meet the staff at Altman and hold open discussion about the trial. Diana showed me a pre/post test they use when training staff about the trial. I thought it was a fantastic idea and has Diana kindly allowed me to share it with you. You will find it attached to the email you received with this newsletter. The site visit was also a good opportunity for Altman to take advantage of my being there to help train new staff that had joined the unit after the initial staff training. I am off to visit the staff in the NICU at the University of Miami at the end of March.

From Diana Hannay:

The site visit helped identify areas in the protocol that were confusing to the staff (like application of the pulse-oximeter and temperature probe) and "helped" renew our enthusiasm for research. Talking with Maureen helped our investigators identify areas in the enrolment process that could be improved so that potential participants are not neglected. Nurse practitioners feel that the study allows us to promote research in our NICU.



## Contacting Valeria

If you need to contact Valeria Rac, the HeLP Trial coordinator, her new email is [helptrials@sunnybrook.ca](mailto:helptrials@sunnybrook.ca)

## Study Materials

Please let Maureen or Valeria know when you are running low on thermometers, wraps, and randomization cards so we can arrange to have supplies shipped to you. **Please note any telephone inquiries about the trial please call Maureen at 416 323 6400 ext 4598.**

## Second Interim Analysis

The next interim analysis will be done once we reach the cornerstone of 50% enrollment (842 babies). Our new statistician Dr. Alex Kiss will be the key person who will run the statistical analyses.

## Reminders

**Remember to fax your randomization cards, even if you do not have VON #, ASAP after delivery to 802 865 9613. Receiving randomization cards on time allows us to keep track of enrollment numbers more accurately. Remember to inform Karla at VON ASAP when a VON number becomes available for a HeLP Trial infant. Remember to pull your randomization cards in numerical order.**

## Randomization

# The trial has now enrolled over 736 infants!

At the end of February we have enrolled: **709 infants** in the main study and **27 infants** in the <24 week gestation pilot study.

**Congratulations everyone! Fantastic work.**

We are still **actively recruiting new sites**; so if you know VON center interested in the trial, please contact Maureen Reilly or Valeria Rac at [helptrials@sunnybrook.ca](mailto:helptrials@sunnybrook.ca)

VON HeLP Trial website: <http://www.vtoxford.org/home.aspx?p=research/help/index.htm> (login: help trial; password: \*babywrap8\*)  
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