



Heat Loss Prevention Trial Newsletter # 11

Thank you to all who attended the HeLP Trial Investigator's Meeting at the VON Annual General Meeting (AGM) on December 1st 2007 in Washington DC. If you are going to PAS in Hawaii and would like to have breakfast or lunch with Maureen, please contact Valeria at helptrials@sunnybrook.ca

Welcome to our tenth 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.

Investigators' Meeting 2007

The HeLP trial investigators meeting was held on December 1st 2007 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. We also want to share the major action points discussed at the meeting that will help us all run this study even more efficiently.

Action points:

- 1) Please fill out the **PIRQ form at 18 months corrected age**. The **Extended follow-up** form must also be filled out if your center is participating in the extended follow up portion of the trial). Forms must be faxed to Ms. Karla Ferrelli at VON. The fax number is 802 865 9613
- 2) Please fill out a **PIRQ form on all infants who have passed away**. Only question 1 has to be answered.
- 3) Please remember to take the **baseline temperature** and record it on the form (Case Report Form 2, Section A, Question 5). The baseline temperature is taken immediately upon arrival in the NICU for an infant who is born and receives initial resuscitation in the delivery room, or if the infant is resuscitated in the NICU, the baseline temperature is taken after cardiorespiratory stabilization.
- 4) To help you determine the corrected gestational age when the PIRQ questionnaire or the extended follow up is preformed please use the **Corrected Age Calculator** on the VON website: <http://www.vtoxford.org/home.aspx?p=research/elbw/index.htm>
- 5) Please make sure that your **IRB/REB renewal is up to date**. We cannot process any data on infants enrolled in your center without the updated letter from your IRB/REB
- 6) Don't forget to **fax us** here at Sunnybrook (416-323-6011) the renewal letter once you receive it from your IRB/REB
- 7) Please make sure that you have enough supplies and randomization cards. If you are running low, let Valeria know at helptrials@sunnybrook.ca
- 8) We are always happy to organize **additional trial training** for any of your staff. Please do not hesitate to contact Maureen or Valeria if you think your staff might benefit from this.

Trial Registry with Clinicaltrials.gov

The HeLP Trial has been registered with the international agency recommended by our funders (Canadian Institutes of Health Research): www.controlled-trials.com (ISRCTN85045728). We are now also registered with The National Institutes of Health at

www.clinicaltrials.gov. (NCT00607464). American IRBs may want to know this information. Please include this information in with your next IRB renewal.

Contacting Valeria

If you need to contact Valeria Rac, the HeLP Trial coordinator, her new email is 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.

Randomization

The trial has now enrolled over 600 infants!

At the end of February we have enrolled: **577 infants** in the main study and **24 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

First Interim Analysis

The results of our first interim analysis are in. The DMSB has reported no safety concerns surrounding the study procedures and recommends that the trial continue enrollment according to the protocol.

You will receive a separate email with a letter regarding the DSMB's report to submit to your IRBs shortly.

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.

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

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HeLP Trial Coordinating Center:

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Coordinator: Valeria: helptrials@sunnybrook.ca