



Heat Loss Prevention Trial Newsletter # 16

The HeLP Trial Investigator Meeting will be nested into the VON Trials Planning Reception on Saturday, December 5th in Washington DC from 17:30-19:00 in the Palladian Ballroom. Contact Valeria (Helptrials@sunnybrook.ca) for more details. Hope to see you there!

Welcome to our 16th 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.

Follow-up Forms (PIRQ and Extended Follow-up)

Please remember to submit the PIRQ forms on ALL infants enrolled. The PIRQ, the telephone questionnaire, is to be filled out when the infant is 18 to 24 months corrected gestational age. Please fill out PIRQ forms on deceased infants as well.

For those centers participating in our Extended Follow-Up, these forms also needed to be completed and submitted for all enrolled infants in addition to completing the PIRQ form.

Reimbursement – Second Checks

The second round of checks will be mailed out at the end of the study. Please make sure to complete and submit all required data forms to VON in order to qualify for the payment.

Second Interim Analysis Update

We are approaching our second interim analysis that will be done once we reach the landmark of 50% enrollment (802 babies). Along with the interim analysis, our biostatistician, Dr. Alex Kiss will run additional analyses to see if the

trial should be stopped early. We will communicate the results of these analyses with all our centers as soon as they become available.

Randomization

The trial has enrolled over 800 infants!

As of the end of October we have enrolled 818 infants: **786 infants** in the main study and **32 infants** in the <24 week gestation pilot study.

Congratulations everyone! Fantastic work.

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.

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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