



# VON HeLP Trial Heat Loss Prevention Trial Newsletter # 10

## Fall 2007

HeLP Trial Investigator Meeting/reception will take place during the VON Annual General Meeting on December 1<sup>st</sup> in Washington DC from 1730-1830 in the Congressional Room. Contact Valeria ([Lubomira.Slatkovska@sunnybrook.ca](mailto:Lubomira.Slatkovska@sunnybrook.ca)) for more details

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.

We will have the next investigator meeting during the VON Annual General Meeting on December 1<sup>st</sup> 2007 in the Congressional Room, Omni Shoreham Hotel, Washington DC, from 5:30 - 6:30pm.

### Welcome New Sites

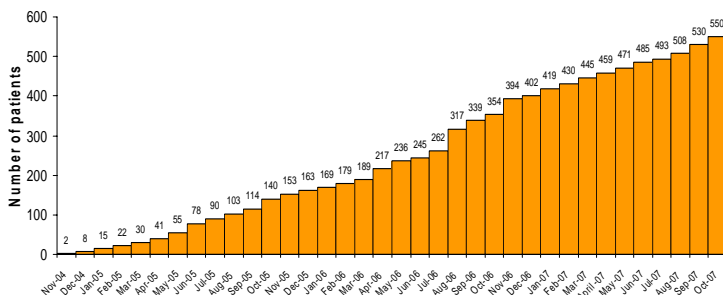
Welcome NYU Tisch Hospital and congratulations to Jackson Memorial Hospital who just recently joined the trial and enrolled 3 infants in October.

### Randomization

As of the end of October we have been enrolled **539 infants** in the main study and **21 infants** in the <24 week gestation pilot study. Congratulations everyone.

We are still **actively recruiting new sites**; so if you know VON center interested in the trial, please contact Maureen Reilly.

HeLP: Cumulative Patient Enrollment



### First Interim Analysis

Many randomized controlled trials have interim analyses to ensure participant safety. If the interim analysis shows that there is overwhelming evidence that a treatment causes or prevents harm, then a study may be stopped prematurely. We reached the number for our first interim analysis in February. After obtaining data on our primary outcome by August, we sent the blinded data to our statistician where it is currently being analyzed and a report will be sent to our Data and Safety Monitoring Board for blinded review. Blinding is used to ensure that bias does not affect how the data are interpreted. We expect to have a report from the DSMB in January of 2008.

### Study Materials

Please let Maureen know when you are running low on thermometers, wraps, and randomization cards so she can arrange to have supplies shipped to you.

### Follow Up

It is hard to believe that the HeLP trial has been enrolling for almost three years! Did you know the first enrollments were in late 2004? Time does have a way of flying right by. This means that many of the early enrollments are now eligible for 18 month follow-up. **All infants enrolled in the HeLP Trial will participate in the Parental Interview and Reporting Questionnaire (PIRQ), which is a telephone survey. Our participating centers that have an established follow-up clinic will be performing the PIRQ as well as filling out the Extended Follow-Up (EFU) data forms.**

All the materials needed for the PIRQ and EFU are available on the VON website at this link: <http://www.vtoxford.org/home.aspx?p=research/help/index.htm> You will need a user name: **help trial** and password: **\*babywrap8\*** to access the follow-up manuals and materials.

**The PIRQ questionnaire shown on the website is a sample only. Valeria will mail you the actual survey document to use. Please contact her at [Lubomira.Slatkovska@sunnybrook.ca](mailto:Lubomira.Slatkovska@sunnybrook.ca) if you need more of these surveys.**

Both the PIRQ and the Extended Follow-up (if your center has a follow up clinic) should be submitted on **ALL** infants enrolled in the trial, even if the parents could not be contacted or the infant has died. This information should be recorded on the forms. If you need a current log of all your enrolled infants eligible for follow-up, please contact Karla at [karla@vtoxford.org](mailto:karla@vtoxford.org) and she will email you a copy of this log. Also, your status report will show if you have already submitted PIRQs on your enrolled infants. The status reports are sent out quarterly and are due to go out again in mid to late November.

### 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 check on Form 4, Question 5, whether the measurement for blood sugar is mmol (millimoles/liter) or mg% (milligrams/deciliter). Also note that the notation 'mg/dl' is the same as mg%.**

**Remember to pull your randomization cards in order from the stack/ box? They have already been randomized!**

<b>VON HeLP Trial website:</b> <a href="http://www.vtoxford.org/home.aspx?p=research/help/index.htm">http://www.vtoxford.org/home.aspx?p=research/help/index.htm</a> (login: help trial; password: *babywrap8*)	<b>VON Contact:</b> Karla Ferrelli: <a href="mailto:karla@vtoxford.org">karla@vtoxford.org</a> Fax: 802 865 9613	<b>HeLP Trial Coordinating Center:</b> Tel : 416 323 6400 x 4598, Fax 416 323 6011 Coordinator: Valeria: <a href="mailto:Lubomira.Slatkovska@sunnybrook.ca">Lubomira.Slatkovska@sunnybrook.ca</a>
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