



Heat Loss Prevention Trial Newsletter #4

Thank you to all who attended HeLP Trial Investigator's Meeting at the VON Annual General Meeting (AGM) on December 3rd 2005.

Welcome to our fourth 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.

Investigators' Meeting 2005

During the HeLP Trial Investigators' Meeting at the VON Annual General Meeting (AGM), we had an insightful discussion regarding institutional consent. Institutional consent is where the individual IRB grants consent for study participation rather than the parent or guardian. Institutional consent is only appropriate if several specific criteria, outlined in the Helsinki Declaration, are met. We feel that the HeLP Trial fulfills these criteria. Without institutional consent, infants who experience an emergent delivery are excluded from trial enrollment due to time constraints. Conversely, with institutional consent, all infants will be enrolled which will ensure that our results are generalizable to the entire population as well as offer all eligible infants the opportunity to participate in the trial.

Because of individual state, province or country legislation, institutional consent will not be an option for all of our participating centers. If you are interested in pursuing institutional consent, we are preparing documents necessary for an IRB application at your site.

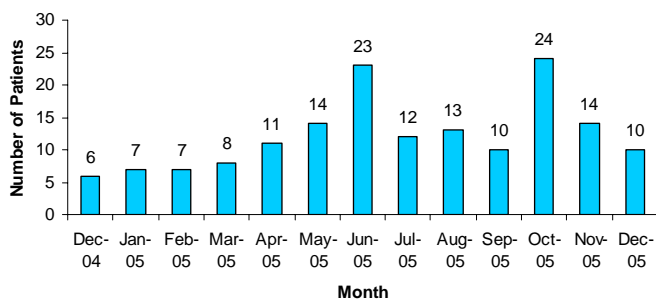
For more information, please view slides from our web conference (<http://www.vtoxford.org/home.aspx?p=research/help/index.htm>) and stay tuned for more detailed information in the near future.

Randomization

We are happy to announce that we now have **161 infants enrolled at 28 centers**, with 6 infants in the <24 weeks strata.

At the AGM, 7 new sites expressed interested in participating in the HeLP trial. Welcome! We are still **actively recruiting new sites**; so if you know of an interested VON center, please contact Luba Slatkovska.

HeLP: Monthly Patient Enrollment



If your center has received IRB approval for the HeLP Trial but has not started enrolling infants, we would love to hear from you and offer assistance in getting started. Please contact Luba.

Reminders

- Please, it is important that you fax all randomization cards to VON as soon as possible after the infant is born (even if you don't have a VON ID number yet). **802 865 9613**.
- HeLP Trial materials are available on the VON website (www.vtoxford.org/home.aspx?p=research/help/index.htm).

Announcements

- We would like to welcome our new HeLP Trial Coordinator, Luba Slatkovska. If you have any questions regarding the HeLP trial, please do not hesitate to direct them to Luba via phone: 416 323 6400 x3033, fax: 416 323 6011, or email: lubomira.slatkovska@sw.ca.

FAQ

Question: Our site is interested in finding our more and possibly applying for institutional consent at our institution. How do we go about it?

Our team is presently working on documents that will familiarize you with the concept of institutional consent. These documents will also assist you with IRB application at your site. We will follow up with you once these documents become available.

Tips from Participating Centers

Tips on achieving high enrollment at you site from Bernice Duesler, MD (HeLP PI @ Temple University Hospital):

- We approach almost 100% of possible candidates for the study. The very few we miss are the mom's that come in quickly and deliver.
- Also we have very few that refuse to enroll in the study. When we approach the mom's, we do bring the wrap. We stress the non-invasiveness of the study. They are not getting any extra medicine or injections; we are trying to keep them warm and not to lose heat and fluid. We explain the thinness of the baby's skin and how quickly they can get cold and we want to find out if the wrap will help. They rarely refuse.
- We have also received a pamphlet from your group several months ago that puts the study in layman's terms. This is helpful and we leave this with them the first time we speak with them. We don't like to hit them with too much the first time we speak to them. We first talk about them having a preemie. We then mention the study, leave the papers and talk about it in more detail during a second or third visit.

Do you have a tip? Please contact Luba.

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