

*****Next HeLP Trial web conference will take place on July 17th 2006 from 1200 to 1330hrs EDT. ***The 2006 VON Annual meeting will be held on Saturday December 2nd. Reserve your hotel now, rooms book up quickly.**

Welcome to our sixth HeLP Trial Newsletter. The purpose of the newsletter 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.

Institutional Consent Update

One of our new HeLP Trial Participating centers from the US has received IC approval without significant difficulties. They will share their experience with the rest of us at our upcoming web conference. Another non-North American center did not receive approval. Their IRB/HREB board did not elaborate as to why in their official response. Several other North American centers are currently in the process of applying.

All forms necessary for IC IRB/HREB application are available on the HeLP Trial Website. Please, contact Luba if you are interested in applying, so we can guide you through the process.

Follow-Up Update

PIRQ follow-up questionnaires, to be filled out on all infants enrolled in the study who survived to discharge, have been mailed to all HeLP Trial participating centers. Please, let us know if you have not yet received PIRQ forms.

For those centers who are participating in the extended follow up, the data forms are available on the VON website.

Please remember that your IRB/HREB must be notified when enrolled infants are reaching the follow up portion of the trial. Some may also request copies of the data forms. **If you have not yet done so, please apply for IRB/HREB approval for the follow-up portion of the study.** Once you receive approval please fax Luba (416 323 6011) your letter of approval. For your convenience, please find a template letter that you may send with your IRB/HREB application on the VON website.

PIRQ only letter:

http://www.vtoxford.org/research/help/FollowUp/HeLP%20PIRQ%20Sample%20letter%20to%20IRB_HREB.doc

PIRQ & EFU letter:

http://www.vtoxford.org/research/help/FollowUp/HeLP%20EFU%20Sample%20letter%20to%20IRB_HREB.doc

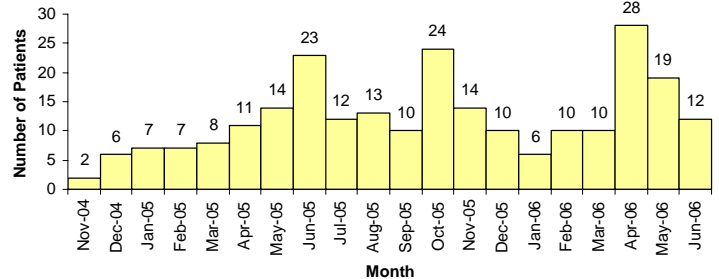
Randomization

We are happy to announce that we now have **246 infants enrolled at 35 centers**, with 9 infants in the <24 weeks strata. We are still **actively recruiting new sites**; so if you know of an interested VON center, please contact Luba.

Welcome new 2006 HeLP Participating centers that are doing an outstanding job in study enrollment: University of Connecticut; Hospital Clinic de Barcelona; Rapides Women's and Children's Hospital; St Luke's Hospital

It's great to have you participating in the HeLP Trial!

HeLP: Monthly Patient Enrollment



Web conference

Next HeLP Trial web conference will be on July 17, 2006 from 1200 to 1330 EDT. Dialing information will be emailed closer to the date.

Our agenda will include and update on the Trial, institutional consent, follow up and new evidence update. If there anything else that you would like to discuss with respect to these or any other topics, please contact Luba.

Reminders

- Please, let us know ahead of time if you are running out of randomization cards or HeLP Trial supplies.
- 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.

FAQ

If a baby was extubated on day X and then re-intubated for less than a day around 2 months after for surgery, what is the date of extubation? Similarly, for CPAP and oxygen, if the baby was on and off CPAP and oxygen, what is the last day for each of them? Since the re-intubation was for surgery and not respiratory failure, put day X as the date of extubation. If you put the latter date (i.e. after the surgery) that would make it look like the infant was intubated for an additional 2 months which is not the case. For CPAP and oxygen, please record the last day on CPAP and oxygen even if the infant has come on and off a few times.

Tips from Participating Centers

You may find it useful to use delivery room information sheets during resuscitation and stabilization. You can use these to collect data (e.g., baseline temperature) that you later transfer to HeLP Trial Form #2. You can also provide yourself with useful reminders on these (e.g., give vitamin K, fax randomization card). Delivery room information sheets are available on VON website in a Word format so you can adapt them to your own needs: <http://www.vtoxford.org/research/help/InfoDeliveryRoomtemplate.doc>

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

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