



Heat Loss Prevention Trial Newsletter #3

HeLP Trial Investigator's Meeting will be held at the VON Annual General Meeting at the Omni Shoreham Hotel on December 3rd from 1730 to 1900 in the Congressional A&B rooms, Washington DC. Hope to see you there.

Welcome to our third 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.

Web conference

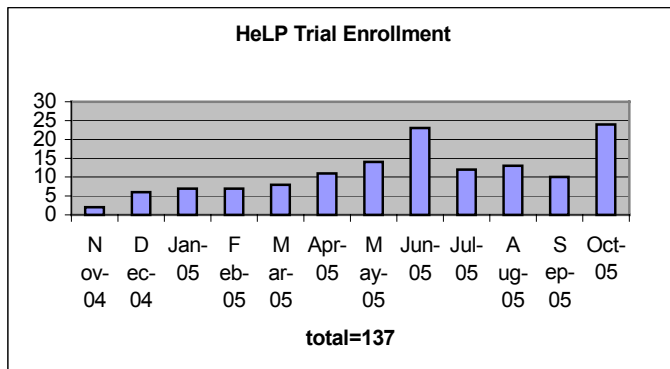
We had our first HeLP Trial Web Conference on October 12th. Due to a technical glitch, the audio for the web conference is not available but the ppt presentation is available on the VON Website.

Sunita led a discussion regarding institutional consent. Institutional consent differs from most other studies (which rely on individual consent), and is only appropriate if several specific criteria are met. For more information, please see the slides from our web conference and stay tuned for more detailed information in the near future.

Randomization

October was a great month for the HeLP Trial. We are happy to announce that we now have 137 infants enrolled at 24 centers. We have 6 infants enrolled in the <24 week pilot study. We are still **actively recruiting new sites**; so if you know of an interested VON center, please contact Maureen Reilly by email at Maureen.reilly@sw.ca or by telephone at 416-323-6400 ext. 3033.

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 Maureen Reilly. Thanks.



Reminders

- HeLP Trial materials are available on the VON website (www.vtoxford.org/home.aspx?p=research/help/index/html). Access to trial forms is password protected. If you do not know the password, please let Maureen know.

- Please try to fax all randomization cards to VON as soon as possible (even if you don't have a VON ID number yet) after the infant is born. [802 865 9613](tel:8028659613).
- Please use the cover sheet when you fax the forms to VON. The cover sheet will guide you in submitting all of the forms
- Please don't forget to send the second pages for forms 2,4, &6. These forms are all two page forms.
- Please try to pull the randomization cards in order so the numbers are sequential. *Many Thanks.*

Data Forms Tips

- Please make sure you use the latest version of the data forms (available on VON website). The forms were updated and released in **July 2005**.
- **Form 3: question 6. Maternal Race/Ethnicity:** please follow the directions found in the MOO on page 36 when filling out this question.
- **Form3: question 7. Maternal Education.** Please try to ask the mother her highest level of education achieved. (MOO pg 37).
- **Form 6: question 1. RDS.** Please check yes only if the PaO2 is <50mmHg in room air, there is central cyanosis in room air, or there is a requirement for supplemental oxygen to maintain a PaO2 of >50mmHg and a chest xray is consistent with RDS (see MOO pg 39).
- **Form 6: question 16. Steroids for CLD:** please only check yes if the infant received **IV** steroids. (see MOO pg 42).

Announcements

- The new **Manual of Operations** (MOO) has been released. It is available on the VON website. Latest version **September 005**.
- The information letter and consent form have been translated into **Spanish**. The translated version is available on the VON website.

FAQ

Question: What do we do if we have pulled the randomization card from the wrong stratum?

Answer: Please fill out Form 7: Protocol Deviation. Section A asks about Randomization Error. Please check yes for question 2: Infant randomized to the incorrect stratum. When we receive the forms we will be alerted to the error in randomization and make sure the infant's data is analyzed according to the proper stratum.

Tips from Participating Centers

I bring a sample of the wrap with me when I am approaching families for consent. It helps them better understand how the wrap works.

Do you have a tip? Please let Maureen know.

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