

Clinical Evaluation Research Unit



The REDOXS[®] Study

REducing DEaths due to OXidative Stress

After a busy summer, we are happy to bring you the next issue of the REDOXS[®] Circular. Read along for an update on enrolment, important notices and frequently asked questions!

Enrolment Update

| # patients enrolled | Site |
|----------------------------------|--------------------------------|
| 14 | Kingston General |
| 2 | St. Joseph's Hamilton |
| 16 | Ottawa General |
| 5 | Ottawa Civic |
| 11 | Sacre Coeur, Montreal |
| 3 | Maisonneuve-Rosemont, Montreal |
| 2 | Royal Victoria, Montreal |
| 2 | Royal Alexandra, Edmonton |
| 55 + 80 (from pilot) = TOTAL 135 | |

1065
patients
to go

Research Team at CERU

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Did you know?

The next start date for new sites is October 2007. We anticipate that another 10 sites will be ready within the next month !!

How to Maximize delivery of enteral study supplements? Discuss these new approaches with your research team

NPO for prolonged periods: To reduce the interruptions to the enteral study supplements, try to limit the NPO period to 2 hours for non-operative procedures, and 6 hours for operative procedures. If you know that the patient is going to be NPO, consider doubling the study supplements in advance. Make sure that the infusion is returned to the regular rate after the "doubling up" to avoid infusing volumes higher than those prescribed.

High gastric residual volumes: High gastric residual volumes are common in critically ill patients and the use of motility agents is recommended as a strategy to minimize these. The combination of erythromycin plus maxeran in particular, is considered to be safe and effective in such patients. Please discuss the option of prescribing this combination with your site investigator.

Small Bowel Feeding: Feeding REDOXS[®] patients via the small bowel may be beneficial in improving the delivery of not only the enteral study supplements, but also enteral nutrition. We are working with Cook Medical to supply interested REDOXS[®] sites with a few self-advancing nasal jejunal feeding tubes (Tiger Tubes[™]). The use of these tubes is **completely voluntary** and they are to be considered a "tool" to optimize the delivery of enteral study supplements/enteral nutrition. If you are interested, please contact Rupinder Dhaliwal to arrange inservices by Cook Medical. Look out for our REDOXS[®] Bulletin Small Bowel Feeding, coming soon.

www.criticalcarenutrition.com
click on THE REDOXS[®] Study

New Resources on our website

Coming soon

Revised Study Procedures
Manuals and other tools

(version September 21st 2007)





Web based data entry: new locking and patient finalizing features

We have built in a feature that will allow you to LOCK the patient's data after the first stage of data entry is complete and FINALIZE the patient when the final stage of data entry is complete.

Locking: At the time of entering **ICU Outcomes** or **Infection Adjudication**, you will be asked whether you are ready to lock the patient's chart or not. Make sure that the data you have entered is accurate. Once locked the data can be unlocked by contacting CERU. After you lock the data, you can still access the Hospital Outcomes, 3 & 6 month and SF-36 pages (if applicable).

Finalizing Patient: When you enter the last outcomes and you click on the **Investigator Confirmation Form**, you will be prompted to finalize the patient. Once the patient has been finalized, you will not be able to make any changes to the data but changes can be made by CERU. **Make sure that the data you have entered is accurate before you finalize the patient.**



Jennifer Korol, our database manager will be contacting some of you to guide you through this new locking/finalizing process.

NOTE: Changes to Antibiotics

Effective immediately, you do NOT have to record changes in the dose/route/frequency of antibiotics as a separate entry. This also means that there are only 2 questions instead of 3 that need to be addressed when determining if there is a suspicion of ICU acquired infection. Please remove the circled question from your checklists (see below):

| | | |
|--|--------------------------------------|-------------------------------------|
| Is this antibiotic prescribed for prophylaxis? | <input type="radio"/> Yes | <input checked="" type="radio"/> No |
| Is this a dose adjustment of an antibiotic previously ordered for an infection? | <input type="radio"/> Yes | <input checked="" type="radio"/> No |
| Is this antibiotic a substitute for an antibiotic previously ordered for an infection? | <input checked="" type="radio"/> Yes | <input type="radio"/> No |

Pharmacy Alert !!



Concern regarding Hypernatremia and Saline

In the event that a patient is hypernatremic and there is concern about infusing additional sodium, the parenteral study supplements can be mixed with D5W instead of normal saline. Compatibility studies done with the parenteral supplements showed that the supplements can be mixed with either D5W or normal saline.

This change has been added to the revised version of the Pharmacy Manual and Study Supplements Manual (September 21st 2007) which will be available soon!

Good Questions !!

Study Day 1: Patient may not get randomized on this day and may not receive any supplements on this day. Do I still call this Study Day1?

Yes, call this study day 1. Since study day 1 is from ICU admission to the end of your flowsheet, it may be that patient does not get randomized until the next day and that supplements do not get started until the next day (e.g. patient is admitted in the middle of the night or early am).

Thanks to Pia Ganz for asking this question

Volume of study supplements within the 24 hr period: What if this is more than the prescribed volume? Do I need to fill out a protocol violation form?

No, you do not need to fill out a protocol violation form but you must write a comment on your daily checklist. When you enter this volume online, you will be prompted to add the reason why the volume exceeded the prescribed. In the event of a major discrepancy e.g. entire 24 hr volume received in 1 hour, please contact the Project Leader.

Thanks to Mary-Jo Lewis for asking this question

Calories from Propofol: Do I calculate these even if patients are not receiving enteral or parenteral nutrition?

No, calories from propofol are to be calculated only if the patient is receiving enteral or parenteral nutrition.

Thanks to Tracy McArdle for asking this question

Changes to data: I accidentally added extra days for the daily data field. How do I delete extra days from the daily data? Can I change the data entered on the screening forms after I have randomized a patient?

To delete extra days, go to the Patient Status Page, click on the last day that you entered data on and scroll down to the bottom, click on the DELETE DAY button. Changes to the screening data after you have randomized can only be made by CERU.

Thanks to Carole Sirois and Johanne Harvey for asking these questions

