The REDOXS© Circular

February 2008 Issue # 7

Clinical Evaluation Research Unit

The *REDOXS*© Study
REducing Deaths due to OXidative Stress

Enrolment Update as of February 29, 2008

Sites Currently Enrolling	Total Enrolments	February Enrolments
Kingston General	27	4
St. Joseph's Hamilton	4	0
Ottawa General	29	3
Ottawa Civic	16	3
Vancouver General	3	0
Sacre Coeur, Montreal	18	1
Maisonneuve-Rosemont, Montreal	8	0
Royal Victoria, Montreal	8	1
Royal Alexandra	7	1
Grey Nun's, Edmonton	2	1
London Health Science Centre	2	1
Health Science Centre, Winnipeg	2	0
Montreal General	1	1
CHUV, Switzerland	1	1
128 + 80 (from pilot) = 208 total		

992 patients to go

While we were short of our goal of 28 enrolments in February with only 17 patients, we are excited about the month of March. We have 14 sites currently enrolling and 7 sites ready to enrol; including a site in Switzerland and Belgium. Please aim for an enrolment goal of 2 patients per site per month.

Study Enrolment	
January	16 pts
February	17 pts

Research Team at CERU

Daren Heyland
Rupinder Dhaliwal
John Muscedere
Jennifer Korol
Daphne Mayer
Suzanne Biro

Congratulations to both Montreal General and CHUV (Switzerland) for enrolling their first patients in the REDOXS© Study.

Reminder about Study Days

For sites who have flow sheets that DO NOT run midnight-to-midnight, there has been confusion around the definition of STUDY DAY and the date assigned by the computer in the eCRF. The confusion arises when there is an ICU admission time after midnight but before the end of the flow sheet and how the computer assigns the date for daily data entry.

If you are about to collect data or to enter data in the eCRF for patients that are admitted after midnight, please contact Daphne Mayer to discuss. If there isn't a clear understanding around this issue there is potential for data to be entered incorrectly. A reference tool is under development and will be emailed to Research Coordinators and will also be available on www.criticalcarenutrition.com in the near future.

P ha

Visual Inspection

Pharmacy staff need to remember to visually inspect the study supplements upon receipt and before dispensing. The Dipeptiven should be clear and colourless. Occasionally, orange-red particles have been observed in some of the enteral products. Fresenius Kabi has indicated that these particles are **NOT** a concern. If you observe these particles you can continue to use the product but please inform us.

REDOXS© Study Contact Information

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Exclusion Criteria

After reviewing the preliminary data entered thus far, we noticed that for a few eligible but not randomized patients the reasons given for not being randomized were actually exclusion criteria. In other words, these patients met an exclusion criteria and it was not necessary to enter information on the Pre-randomization screen of the eCRF.

The given reasons in question were as follows:

1. > 24 hrs from ICU admission
2. Patient enrolled in a another clinical trial

These are both exclusion criteria.

Please ensure that the patient does not meet an exclusion criteria before you select *None of the Above* on the Exclusion Criteria page of the eCRF.

Reminder: Other ICU studies

Co-enrolment in other ICU interventional studies is permitted. However, if it is a related study (i.e. similar interventions designed to influence outcome measures) co-enrolment is not permitted.

Co-enrolment of REDOXS patients **is permitted** in the following studies:

PROTECT
ABATE
OSCILLATE

Co-enrolment of REDOXS patients **is NOT permitted** in the following studies:

SUGAR

Industry sponsored studies generally do not permit co-enrolment but there may be exceptions. If you are unsure if co-enrolment is permitted in a particular study, please discuss with the Site Investigator or contact Daphne Mayer, Project Leader.

Propofol

A number of sites have inquired about the contribution of propofol calories to total energy. We have addressed this on page 37 of the Implementation Manual and page 7 of the Dietitian Manual; however some clarification is needed.

Propofol kcalories are added to total energy for Parenteral Nutrition **only** if the propofol is continuously infused for ≥ 6 hrs within your 24 hr flowsheet period (i.e. within a study day). If the propofol is infused for < 6 hours or is an intermittent dose the calories from propofol should not be included in PN Total Energy. It is not required to separately identify the propofol on the eCRF, but the site dietitian may want to keep record of the energy contribution from propofol on her daily work sheet in case a discrepancy is found during source verification. (Thanks to Ella Mann & Amber Robinson, Kingston General Hospital and Audrey-Anne Gosselin, Sacre-Coeur for highlighting this concern.)

Antibiotics - Did you know?

1. When you record all antibiotics started within the period of 7 days prior to ICU admission, we are **only** referring to the current hospital stay before ICU admission, if applicable. We are not asking you to collect data for other hospital stays that may have occurred shortly before the current stay or for antibiotic use at home.
2. When you are entering antibiotics into eCRF, you do not need to record any changes in dose, route or frequency as a separate entry. A separate entry is warranted if the antibiotic is held for > 48 hours. (See page 45 of the Implementation Manual for more details.)

Randomization

1. If there has been an error in randomization....please call us ASAP.
2. If you have accidently randomized the same patient twice, please call us ASAP so that we can have our IT staff fix this in our database BEFORE you randomize the next patient.

Locking Patients

Please remember to lock your patients so that we can move forward with source verification at your site.

Refer to page 50 of the Implementation Manual for more details

Good Questions !!

What documentation is required if a REDOXS patient is re-admitted to the ICU > 48 hours after the ICU discharge?

No documentation is required because the re-admission is >48 hours from ICU discharge. We have outlined in the REDOXS© Implementation Manual (page 7) that if a patient is re-admitted to your ICU **within 48 hrs** of discharge, consider this to be a continuation of the previous stay. Restart the study supplements and continue to collect data and consider the reason for re-admission to ICU as a Serious Adverse Event. If a patient is re-admitted to your ICU after 48 hours of discharge, this is not considered to be a continuation of the previous stay.

Thanks to Norine Whalen for the question

The family decided that treatment/care should be withdrawn and as such data collection stopped. The patient died in the afternoon the following day. When I try to enter the date of death in the outcomes section, I receive an error message indicating that no data has been entered on the date of death. What do I do?

Because the duration of data collection is until day 30 **or** until ICU discharge **or** until time of death, the system identified that data was missing for the period of time before death actually occurred (from the start of the flow sheet until death) thus the error message. You will not have any data to enter because data collection was stopped. In the eCRF on the day of death you will need to click *N/A* or *No* for each data component.

Thanks to Ella Mann for the question