The REDOXS© Circular

May 2008 Issue # 10

Clinical Evaluation Research Unit

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

Patient Enrolments in 2008	
January	16 pts
February	17 pts
March	17 pts
April:	17 pts
May	**18 pts.**

940 patients to go

Congratulations to Fiona Auld and colleagues at Royal Jubilee for helping us get over the 17 patients/month hump we've been experiencing over the past 4 months. Royal Jubilee in Victoria, BC, one of our newest sites, enrolled their first patient on May 31, 2008. Great Job!!!.

The top 3 enrolling sites for the month of May were Ottawa General and Kingston General Hospital with 4 patients each, and Sacre-Coeur with 3 patients.

ICU Acquired Infections

In order to effectively adjudicate ICU acquired infections, accurate microbiology and antibiotics data must be entered into the eCRF for each patient. A suspected ICU acquired infection is suggested if there is a positive culture and/or an antibiotic is ordered, after 72 hours from ICU admission.

After these first 72 hours, there are two questions for both positive cultures and antibiotics that MUST be answered by the site investigator or delegate.

For positive cultures:

- Is this culture a manifestation of a previously diagnosed infection?
- Is this a routine swab?

For antibiotics:

- Is this antibiotic prescribed for prophylaxis?
- Is this antibiotic a substitute for an antibiotic previously ordered for an infection?

Based on the responses to these questions the electronic data capture system will prompt the Research Coordinator that the infection must be adjudicated by the Site Investigator.

It is essential that the Research Coordinator and the Site Investigator work collaboratively throughout this process.

Attention Research Coordinators

You will be hearing from us shortly about a conference call to be scheduled with all Research Coordinators as a group. The purpose of this call is to present our newly developed training tools addressing SAE reporting, long term follow-up and obtaining consent. Additionally, we will discuss how to use the information in the newly revised site periodic report.

Site Reports: Monthly report vs. Periodic report

The **monthly report** provides information about your site's enrolment each month.

The **periodic report** highlights quality issues, such as study supplement compliance, at your site over a specified period of time.

Enrolment Update as of May 31, 2008

Sites Currently Enrolling	Total Enrolments	May Enrolments
Kingston General	35	4
St. Joseph's Hamilton	7	2
Ottawa General	40	4
Ottawa Civic	20	0
Vancouver General	4	0
Sacre Coeur, Montreal	23	3
Maisonneuve-Rosemont, Montreal	8	0
Royal Victoria, Montreal	8	0
Royal Alexandra	8	1
Grey Nun's, Edmonton	5	1
Victoria General	1	1
London Health Science Centre	5	1
Health Science Centre, Winnipeg	3	0
Queen Elizabeth II HCS (Halifax)	1	0
Montreal General	7	0
L'Enfant Jesus (Quebec City)	1	0
CHUV, Switzerland	3	0
Royal Jubilee Hospital, Victoria, BC	1	1
180 + 80 (from pilot) = 260 total		

REDOXS© Study Contact Information

Daphne Mayer, Project Leader, 613 549 6666 ext 2834; mayerd@kgh.kari.net
Rupinder Dhaliwal, Project Leader, 613 549 6666 ext 3830; 613-484-3830 cell phone; dhaliwar@kgh.kari.net

Organ failures - timing of onset

From our Source Verification visits we have noticed some issues with the timing of organ failures recorded in the eCRF.

In the consideration of the eligibility of a patient for the study, the organ failures may start before ICU admission, but have to be present in the ICU. (Note: the failures may have resolved by the time of screening or randomization). See page 13 of the REDOXS© Implementation Manual for more information.

We are asking you record the START of the organ failure. Accordingly, it is important to go back far enough in the patient's chart to determine the correct date and time.

Please note that we are only interested in acute organ failures and therefore anything that occurs 72 hrs before ICU admission would not meet the inclusion criteria.

Inclusion Criteria - Low platelet count

One of the criterion that can be meet for inclusion into the study is a platelet count < 50mm^3.

Teresa Morrison, a Research Coordinator at London Health Sciences Centre, asked whether chemo induced- or chronic thrombocytopenia should be considered in the determination of the eligibility of the patient. This condition is not considered acute in terms of the organ failure. But this type of patient would be considered eligible if they met 2 of the remaining organ failures, and did not meet any exclusion criteria.

Research Team at CERU

Daren Heyland

Rupinder Dhaliwal

John Muscedere

Jennifer Korol

Daphne Mayer

Suzanne Biro

Erythromycin:

If erythromycin is prescribed as a motility agent, please record it as such in the eCRF. Do not enter it as an antibiotic.

Antibiotics

Please note, that fusidic acid and famcyclovir were added to the antibiotic taxonomy.

What do you think?

At this point you should have had the opportunity to review your site's monthly report. A newly revised periodic report will follow soon. We would like to hear your feedback. Do you find these reports helpful? What kind information would you like to see in these reports? Please send your questions or comments to Daphne Mayer, Project Leader at mayerd@kgh.kari.net

SF36 & Source Verification

When administering the SF36 questionnaire, please use a paper copy to record the respondent's answers. The paper copy must be kept for source verification.

Pharmacy

Please remember that the REDOXS Project Leaders, Rupinder Dhaliwal and Daphne Mayer, are both blinded. If you have questions, issues or concerns about specific supplements for particular patients, it is IMPORTANT that you maintain the blind when in correspondence with us. If you are unsure whether you can discuss the issue without unblinding, please contact Suzanne Biro, Project Assistant. Suzanne will relay your concern to the Project Leaders without revealing any specifics.

Good Questions !!

I have a REDOXS© patient who is no longer receiving study supplements because IV and GI access are no longer clinically required, and orders have been written to discharge the patient from ICU. The problem is that the patient needs to wait around in the ICU for a couple of days until a bed becomes available. Which date do I enter in the eCRF, the discharge order date or the actual discharge date?

You must enter the actual discharge date. Also, you need to enter the available data components for the length of the study period; which in this case is until the patient is actually discharged from the ICU. If this data is not entered you will get an input warning.

Thanks to Amber Robinson, KGH & Tracy McCardle, Ottawa General for this question

I have a REDOXS© patient who received study supplements for 24 hours, but was then extubated and discharged to the floor. Parenteral supplements are being continued on the floor for 120 hours from time of randomization. The next day a feeding tube was reintroduced, should I restart enteral supplements? For how long?

Yes, restart enteral study supplements. Since the patient is on the floor and spent <5 days in the ICU, the enteral study supplements would only run until the end of 120 hrs from time of randomization.

Thanks to Leslie Atkins, Royal Jubilee/Victoria General