October 2009 Issue #28

The REDOXS© Circular

The REDOXS® Study
REducing Deaths due to OXidative Stress

As of October 31st, 2009

Canada

Site #	Institution	Oct	Cumulative
1	Kingston General Hospital	2	67
2	St. Joseph's Healthcare	5	43
3	Ottawa General	6	109
4	Ottawa Civic	1	41
5	Vancouver General	-	19
6	Sacre-Coeur, Montreal	3	59
7	Maisonneuve-Rosemont	-	13
8	Royal Victoria, Montreal	1	9
9	Royal Alexandra, Edmonton	-	18
11	Grey Nun's, Edmonton	-	14
13	Victoria General	1	6
14	London HSC	-	12
15	HSC Winnipeg	-	8
16	Queen Elizabeth II, Halifax	1	11
17	†Sunnybrook, Toronto	-	2
18	†St. Paul's, Vancouver	-	6
19	Montreal General	-	10
20	Enfant-Jesus, Quebec City	1	20
23	Royal Jubilee, Victoria	1	7
25	Mount Sinai, Toronto	3	23
29	St. Boniface, Winnipeg	-	-
32	University Hospital, London	2	5
33	Laval, Quebec City	1	1

† Screening activities have been stopped, site closing out

Cumulative Enrollment: 643
(includes 80 patients from pilot)

Patients enrolled in October: 34

United States

Site #	Institution	Oct	Cumulative
26	University of Colorado	2	15
27	Miami Valley, Ohio	-	4
28	Fletcher Allen, Vermont	-	6
30	University of Louisville	1	9
31	University of Texas	-	1

Europe

Site #	Institution	Oct	Cumulative
21	Liege, Belgium	2	5
22	CHUV, Switzerland	-	9
24	UZ Brussels, Belguim	-	2
35	Kiel	-	2
36	Lübeck	-	-
37	Greifswald	1	5
38	Hamburg-Altona	-	2

Great job Marie-Claude Ferland at Hôpital Laval for enrolling your 1st REDOXS patient!

Fantastic work Laura Banici for re-commencing screening activities at the Royal Victoria in Montreal and for enrolling a patient at that site.

Congratulations to all sites who enrolled patients this month. October is our highest enrolling month to date!!!

40 a month for the next 14 months

In order to complete patient enrollment by the end of 2010 we must enroll 40 patients each month. In October we only fell slightly short of that monthly target. Let's build on the momentum gained in October and see if we can reach our target of 40 patients/month.

Interim Analysis: Target Date

We require 600 locked patient eCRFs to conduct this analysis (i.e. data collection completed up to an including ICU/Hospital Outcomes).

As of 27-Oct-09 we have 516 locked charts (this includes those charts already finalized). We have established a target date of 31-Dec-09 for sites to complete the remaining 84 eCRFs. Your efforts to reach this target are very much appreciated!

FAQs

Is it acceptable to co-enroll patients in the REDOXS and OSCILLATE studies?

The consensus of the REDOXS Steering Committee and the OSCILLATE PIs is that it is acceptable to co-enroll patients in these two studies.

Why is it preferable for parenteral study supplements to be infused via a central line?

The parenteral study supplements should be given via a central line. It is a high osmolality solution and may cause phlebitis but it is certainly permissible to use peripherally up to 72 hours and watch for signs of phlebitis.

Tips from the Data Management Team

What do I enter if, when calculating an APACHE II score, I only have one value for a physiological parameter (e.g. WBC)?

In these instances, simply enter the one available value as both the "high" and "low" value. You can NOT enter a "0" because the form will not calculate the APACHE II score appropriately.

Primary Reason for Admission to the ICU

We remind sites to record the most responsible reason for a patient's admission to the ICU. Based on recent data reviews, we have noted that presenting symptoms at the time of ICU admission are being recorded as the Primary Admission Diagnosis. Though the only information available at the time screening may be these presenting symptoms, we ask that you seek the definitive reason, which may be available after a day or two, this is the reason that should be recorded in the eCRF.
For example, a patient presents to the ICU in respiratory distress/failure. The question is, what caused the respiratory distress/failure? In this instance it was determined that the patient had a bacterial pneumonia. As a result, you would chose Bacterial/Viral Pneumonia.
Remember to be as specific as possible.

Coming in 2010!

- Interim Analysis
- Periodic Reports
- DMC/Steering Committee Meeting
- Research Coordinator Meeting

This month, all site pharmacies will be receiving new inventory for the Enteral REDOXS© Study Supplements to replace inventory that will expire at the end of November 2009. At the end of the month, please ensure that all study supplements are recorded on the appropriate nutrient accountability logs before disposing of the expired products. Expired study supplements may then be disposed of according to your site-specific drug destruction policy.

The Faces of REDOXS©

University of Colorado Denver
Department of Anesthesiology

Pictured to the left is Dr. Paul Wischmeyer's team at the University of Colorado Denver.

Since beginning patient recruitment in December 2008 the Colorado team has enrolled 15 patients into the REDOXS study, our highest enrolling US site! The University of Colorado is also participating in the REDOXS© Lab Sub Study.

In addition to patient recruitment responsibilities, the University of Colorado acts as the Study Supplement distribution center for our US sites.

Clinical Evaluation Research Unit

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