February 2009 Issue #19

The REDOXS© Circular

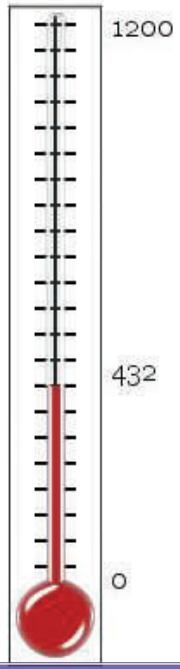
The REDOXS® Study
REducing Deaths due to OXidative Stress

768 patients to go

Enrolment as of February 28, 2009

Site	February	Cumulative Total	Site	February	Cumulative Total
Kingston General	2	51	Sunnybrook, Toronto	-	2
St. Joseph's Healthcare	-	20	St. Paul's, Vancouver	1	6
Ottawa General	4	72	L'Enfant Jesus, Quebec City	2	13
Ottawa Civic	3	32	Liege, Belgium	-	1
Vancouver General	3	17	CHUV, Switzerland	1	8
Sacre Coeur, Montreal	2	39	Royal Jubilee, Victoria	-	3
Royal Alexandria, Edmonton	1	14	UZ Brussels	-	2
Maisonneuve—Rosemount	1	12	Mount Sinai, Toronto	1	5
Grey Nun's, Edmonton	1	10	University of Colorado	2	3
Victoria General	-	3	Miami Valley, Ohio	-	1
London Health Sciences Centre	-	10	University of Louisville	-	-
Health Sciences Centre, Winnipeg	1	8			
Queen Elizabeth II, Halifax	-	5			

Total = 432 *(includes 80 from pilot)*



CERU RESEARCH TEAM

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Enrolment News

The month of February has brought 25 new enrolments. Congratulations to the teams at Kingston General, Ottawa General, Ottawa Civic, Vancouver General, Sacre-Coeur, Maisonneuve-Rosemont, Royal Alexandra, Grey Nun's, HSC Winnipeg, Enfant-Jesus, CHUV, Mount Sinai, St. Paul's Hospital and the University of Colorado for enrolling patients this month. **Keep targeting your 2 patients per month, let's try to exceed 25 patients next month!!!**

March Madness

This month's enrolment challenge is a team effort! We have sorted each site into a team. The team that collectively enrolls the most patients by the end of March will be recognized. Good luck teams!

The challenge is on….

Team A	Team B	Team C	Team D	Team E
Kingston General	St. Joseph Hamilton	Ottawa General	Ottawa Civic	Sacre-Coeur
Enfant-Jesus	Vancouver General	Grey Nun's	Mount Sinai	Royal Alexandra
Rosemont	London HSC	Winnipeg HSC	QE II Halifax	CHUV
Victoria General	Sunnybrook HSC	St. Paul's Hospital	Royal Jubilee	U of Colorado
Liege Belgium	Miami Valley	UZ Brussels	U of Louisville	Fletcher Allen
St. Boniface, Winnipeg				

Ongoing Training

Looking to brush up on Good Clinical Practice? Check out the following links:

ICH Good Clinical Practice

http://www.ich.org/LOB/media/MEDIA482.pdf

Tri-council Policy Statement: Ethical Conduct for Research Involving Humans

http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm

Health Canada Division 5, Food and Drug Regulations

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/reg/1024-eng.php

GCP in FDA-Regulated Clinical Trials

http://www.fda.gov/oc/gcp/default.htm

Study Team Contact Information Updates

We have recently become aware of several changes is staffing at various participating sites that affect our contact and distribution lists. Please inform us of any changes regarding study coordinators, dietitians or pharmacy staff that have occurred in the past 3 months. Send these updated to Suzanne Biro (sbiro@kgh.kari.net) .

New Antibiotics

The antibiotics Micafungin and Anidulafungin have been added to the taxonomies found on the EDC System.

APACHE II—Scoring RR when patient is on HFO

For patients on High Frequency Oscillation (HFO) it would seem that the Respiratory Rate (RR) should be > 50, however this would mean that the patient's APACHE score may be falsely elevated. Instead, we recommend that in the event that a patient is on HFO within the first 24 hours of admission to ICU, the lowest and highest RR used for the APACHE II should be "pre-HFO" RRs.

Frequently Asked Questions

Is a patient with metastatic cancer or Stage IV lymphoma eligible for the study?

This type of patient may be eligible for the study if they have a prognosis with a life expectancy of at least 6 months. This exclusion criteria does not impact the medical safety of the patient, rather it is part of the criteria to attempt to ensure the patient will be available for the 3/6-month follow-ups. Contact the Project Leaders if you have any questions regarding this exclusion criteria.

What time do I use to document onset of organ failures, time of screening or actual onset of organ failures?

The actual time of onset of organ failures should be used for all eligible patients. An exception to this is when screening data for excluded patients is entered. In this case, in an effort to ease the burden of data collection because the EDC System requires an entry, the time of screening can be used. Refer to the table to the right for a description.

Collect the actual time of onset of organ failures	Collect the time of screening as the time of onset of organ failures
(1) Patient meets all inclusion criteria, patient does not meet any exclusion criteria, patient is randomized. (2) Patient meets all inclusion criteria, patient does not meet any exclusion criteria, patient is eligible but not randomized.	(1) Patient meets all inclusion criteria, patient meets exclusion criteria, patient is not eligible.

The Implementation Manual (pg. 13) indicates that the onset of hyperperfusion is defined as the start of vasopressor/inotrope agents for at least 2 hours. What time do I use to record the onset of organ failure, the date/time of start of vasopressor/inotrope agents or the time once they have been receiving them for 2 hours?

When assessing for eligibility for the hyperperfusion criteria, once you have verified that a patient has been receiving vasopressor/inotrope agents for at least 2 hours, go back and use the date/time of the start of the infusions for the documented time of onset of hyperperfusion.

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