The REDOXS© Circular

March 2008 Issue # 8

Clinical Evaluation Research Unit

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

Thank you to all the busy Research Coordinators who continue to screen and enroll patients for the REDOXS© Study.

With enrolments of only 17 patients in March, we are well below our target. Please try to achieve the enrolment goal of 2 patients per site EACH month.

CONGRATULATIONS to the following sites who met or exceeded enrolment goals for March:

Montreal General - 4 enrolments
Ottawa General - 4 enrolments
Ottawa Civic - 3 enrolments
Kingston General Hospital - 2 enrolments

Patient	
February:	17 patients
March:	17 patients

Enrolment Update as of March 31st, 2008

Sites Currently Enrolling	Total Enrolments	March Enrolments
Kingston General	29	2
St. Joseph's Hamilton	4	0
Ottawa General	33	4
Ottawa Civic	19	3
Vancouver General	3	0
Sacre Coeur, Montreal	18	0
Maisonneuve-Rosemont, Montreal	8	0
Royal Victoria, Montreal	8	0
Royal Alexandra	7	0
Grey Nun's, Edmonton	3	1
London Health Science Centre	3	1
Health Science Centre, Winnipeg	3	1
Montreal General	5	4
CHUV, Switzerland	2	1
145 + 80 (from pilot) = 225 total		

975 patients to go

Interruptions of Study Supplements

Study supplements may on occasion need to be interrupted. Situations arise where there is temporary loss of enteral or parenteral access; however, every attempt should be made to ensure compliance with the prescribed amounts of the REDOXS© study supplements (i.e. 480 ml/day enteral supplements and 240 ml/day parenteral supplements).

Remember, you can double up infusion rates of the study supplements either in advance of or after the interruption.

Example: A patient undergoes a procedure and supplements are stopped for 4 hrs. In order to ensure study supplement compliance within the 24 hour study day, you have the option of doubling the infusion rate in the 4 hrs before the procedure or in the 4 hours after the procedure.

PLEASE LOCK YOUR PATIENTS

In the next few weeks we will be preparing for the next Data Monitoring Committee Meeting and we need to generate reports from locked patient data. Please review your outstanding eCRFs and lock applicable patients. Reminder - eCRFs should be completed within 2 months of ICU admission.

Check out page 2 of the REDOXS© Circular to view a visual representation of your site's performance against other REDOXS© sites.

REDOXS© Study Contact Information
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Patient transfer from another ICU to your ICU

For patients that have been transferred to your ICU from an ICU at a different hospital, please remember the following:

- The 24 hour period from ICU admission to time of consent refers to the TOTAL time the patient is in an ICU setting. That is, the 24 hour period begins at the time of ICU admission at the other hospital.
- For example, if a patient is in another ICU for 4 hours and is subsequently transferred to your ICU, then you have 20 hours remaining to obtain consent for enrolment.

Good Clinical Practice: Essential Documents

Curriculum Vitae: We have received some CV's from Site Investigators and sub-investigators. Please send outstanding Delegation of Authority Logs and CV's to the attention of Suzanne Biro, Project Assistant (Fax 613.548.2428; biros@kgh.kari.net).

Please note that in order to comply with Health Canada's Good Clinical Practice Guidelines there is additional documentation that we must collect from each site. In the near future, we will ask for proof of certification/accreditation of the medical laboratory that generates the routine test results you collect for the REDOXS© Study. Additionally, we will ask for the normal values or ranges for these procedures/tests. If you have this information currently available please fax to the attention of Daphne Mayer (Fax 613 548 2428).

NEW ADDITIONS

There have been new additions to the organisms and antibiotic taxonomies in the eCRF.

The following organism was added:

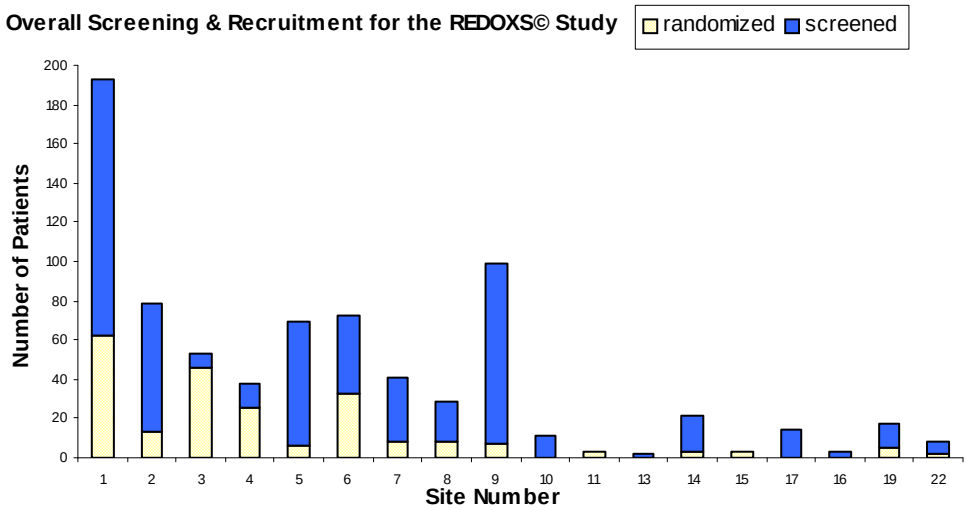
Ralstonia sp.

The following antibiotics were added:

polymyxin E
Tigecycline
DDS (diamino-diphenyl sulphone)

If you cannot find an organism or antibiotic in the taxonomies, please contact Daphne Mayer, Project Leader.

How is your site doing compared to other REDOXS© sites?



1. KGH
2. St. Joseph's
3. Ottawa General
4. Ottawa Civic
5. Vancouver General
6. Sacre Coeur
7. Rosemont
8. Royal Victoria
9. Royal Alexandra
10. Charles Lemoyne
11. Grey Nun's
12. Victoria General
13. Victoria General
14. London HSC
15. Winnipeg
16. Halifax
17. Sunnybrook
19. Montreal General
22. CHUV

Good Questions !!

I am screening a patient that had a closed head injury many years ago and has had a reasonable level of functioning at home. He was admitted to the hospital for renal colic, and now has urosepsis. Does the previous head injury exclude him from the study?

No, the patient does not meet an exclusion criteria. Patients with ACUTE severe acquired brain injury are excluded.

Thanks to Maureen Gardner for the question.

What is the EN stop date:
(1) If the patient continues enteral feeds after being discharged from ICU?
(2) If the patient remains in the ICU beyond day 30 and is still receiving enteral feeds?

(1) If EN continues past ICU discharge, then EN stop date/time = ICU discharge date/time (Pg 29 of Implementation Manual).
(2) If the patient is still in the ICU past day 30 and is still receiving EN, then EN stop date = Day 30 date. EN stop time is the time your flow sheet ends.
In both case, please enter the actual EN stop date in the comments field.

Thanks to Mary-Jo Lewis for the question.