The REDOXS© Circular

December 2007
Issue # 5

Clinical Evaluation Research Unit

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

With 8 new patient enrolments in December, the REDOXS© Study moves forward into 2008. We hope you have had a wonderful holiday season and that you are ready to begin enrolling patients again.

Enrolment Update as of January 9, 2008

# of patients enrolled	Site
22	Kingston General
3	St. Joseph's Hamilton
23	Ottawa General
10	Ottawa Civic
3	Vancouver General
17	Sacre Coeur, Montreal
8	Maisonneuve-Rosemont, Montreal
6	Royal Victoria, Montreal
6	Royal Alexandra
1	London Health Sciences
1	Health Science Centre, Winnipeg
99 + 80 (from pilot) = TOTAL 179	

1021 patients

Monthly Enrolment

November:	**21 patients**
December:	**8 patients**
January:	**4 patient (to date)**

Research Team at CERU

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

REDOXS Study Contact Information

Daphne Mayer, Project Leader is available to address your issues and concerns. Please feel free to contact her.
613 549 6666 ext 2834
mayerd@kgh.kari.net

Rupinder Dhaliwal, Project Leader, will be focusing on the setup of new REDOXS sites. Rupinder is still available for urgent or after-hour calls.
613 549 6666 ext 3830
613-484-3830 cell phone
dhaliwar@kgh.kari.net

Eligibility and Timing of Organ Failures

We have had several questions about the timing of organ failures and patient eligibility. Organ failures may have started before ICU admission but **must be present in the ICU** in order to meet the inclusion criteria. A patient remains eligible for enrolment even if organ failures have resolved at the time of screening or randomization. If organ failure has occurred > 72 hrs prior to ICU admission, it may not be considered acute. Contact the site investigator to discuss this issue.

Try to answer the following questions about this hypothetical case.

If you screen at 09:00 hrs, is this patient eligible for inclusion? What is the timing of organ failures?

16:10 hrs Patient admitted to ER, SOB, ABGs PF ratio 240
16:40 hrs in ER intubated on mechanical ventilation
16:50 hrs in ER dopamine started 6 µ/kg/min until 18:00 hrs
17:00 hrs in ER ABGs PF ratio 210
19:00 hrs transferred to ICU
20:00 hrs started on dopamine at 8 µ/kg/min until 24:00 hrs
21:00 hrs in ICU ABGs PF ratio 212
24: 00 hrs in ICU dopamine d/c
(Answer at the bottom of page 2)

www.criticalcarenutrition.com
click on The REDOXS© Study

Check out the latest additions to the REDOXS© website

- **Improved Worksheets and Checklists**
- **Daily Monitoring Logs**

(version December 10, 2007)

Duration of Data Collection

Daily data, daily nutrition data, vasopressors and concomitant medication data **must be collected from STUDY DAY 1 and each day until DAY 30, ICU discharge or death.** There are a few exceptions:

(1) Study Supplementation compliance data is collected for a maximum 28 days from randomization.

(2) Microbiology data collection must start, if applicable, 7 days prior to ICU admission and continue until Day 30, ICU discharge or death.

(3) Antibiotic data collection must start, if applicable, 7 days prior to ICU admission and must continue until antibiotics are discontinued, possibly beyond ICU discharge.

Need REB Acknowledgement for SAEs

For our records, we need documentation that your REB has either received or been sent all site SAE reports. Please fax documentation to Daphne Mayer, Project Leader (613 548 2428)

Strongly Recommended: Daily Monitoring Logs

In the event of a Health Canada Audit, we must ensure that you, the participating sites, are monitoring the following components of data collection in real time:

Study supplement compliance
Serious Adverse Events

We also recommend that other elements such as **Microbiology** and **Antibiotic** data also be collected close to real time in order to make the ICU infection adjudication process easier for you.

Attention Research Coordinators: We will be looking for this information when we visit your site during source verification, therefore we created a Daily Monitoring Log that may assist with this specific data collection. Shortly, we will send out an email with these logs for your review. Please feel free to use this tool if you find it helpful. Additionally, we thought this log would assist you in the transferring of date to the Electronic Case Report Forms.

Web Based Data Entry

Outcomes and Follow-up: In order to proceed to Outcomes and Follow-up in the data capture system, all input warnings and yellow or red flagged fields must be addressed

REB Renewal Dates

You cannot enrol patients if your REB approval has expired. Since we are starting a new year, please check your REB expiry dates. There are a number of sites who will be expiring in the coming months.

Exclusion Criteria: GI Contraindications

Many sites are having difficulty with starting the enteral study supplements on patients with GI interference. An absolute contraindication to enteral study supplements would include GI perforation, obstruction or no GI tract access for any reason.

Please note that the enteral study nutrients are infused at only 20 ml/hr and are absorbed in the proximal small bowel. Data suggests that glutamine has a positive impact on GI impairment (the placebo will have no effect on the bowel). Procedures such as bowel surgery (i.e. colectomy) are not contraindications to enteral study supplements.

Pharmacy News

Did you know?

A three-day quantity of parenteral supplements can be prepared ahead of time….this may help reduce workload on the weekends. Prepare three parenteral bags on Friday for use Saturday, Sunday and Monday. Once made up the Parenteral solution has a shelf life of 96 hours.

Good Questions !!

Disposing of study supplements: Do returned, unused study supplements and empty vials need to be kept for monitoring purposes?

No, unused and returned or expired study supplements and empty vials do not need to be kept for monitoring purposes. Record unused product returned to the pharmacy or expired product in the Nutrient Accountability Log. Please dispose as per your pharmacy's drug destruction policy.

Thanks to Marceline Quach for asking this question

Delivery of Parenteral Study Supplements: Can the study supplements be piggybacked in through the same IV line that is infusing PN containing heparin or insulin or through the same line that is infusing heparin or insulin?

No. Currently there is no stability data for the study supplements administered via a conventional Y-set with PN admixtures, heparin/insulin infusions or other medications. As such, piggybacking the study supplements with heparin or insulin should be avoided. In this case you must use a separate line for the Parenteral supplements.

Thanks to Lisa Julien, Norine Whalen & Pat Thompson for asking the question.

Answer: Yes the patient meets the inclusion criteria.
The 1st organ failure was @ 17:00 in the ER (still present in in ICU @ 21:00). The first organ failure was not at 16:10 (PF ratio = 240) because patient was not mechanically ventilated.
Refer to page 13 of the Implementation Manual for more details.
The 2nd organ failure was @ 20:00 in the ICU where patient received 8 µ/kg/min for ≥ 2 hrs. The 2nd organ failure was not at 16:50 in the ER because patient received vasopressors for ≤ 2 hrs.