The REDOXS© Circular

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Clinical Evaluation Research Unit

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

Research Team at CERU

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Thank you to all for a successful January. We enrolled 16 new patients and look forward to increasing the number of enrollments in February.

Enrolment Update as of February 14th 2008

999
patients to go

# of pts enrolled	Site
25	Kingston General
4	St. Joseph's Hamilton
29	Ottawa General
15	Ottawa Civic
3	Vancouver General
17	Sacre Coeur, Montreal
8	Maisonneuve-Rosemont, Montreal
7	Royal Victoria, Montreal
7	Royal Alexandra
2	London Health Sciences
2	Health Science Centre, Winnipeg
2	Grey Nun's, Edmonton
121 + 80 (from pilot) = 201 TOTAL	

***CONGRATULATIONS** to the following Research Coordinators who have enrolled patients into REDOXS© in February so far:*

- ***Sharlene Hammond, Ella Mann & Amber Robinson @ KGH - 2 patients***
- ***Tracy Mcardle, Irene Watpool & Claude Gaudert @ Ottawa General - 3 patients***
- ***Mary Jo Lewis & Julia Foxall @ Ottawa Civic - 2 patient***
- ***Jennifer Barchard & Michael Krause @ Grey Nun's (Edmonton) - 1 patient***
- ***Teresa Morrison @ London HSC - 1 patient***
- ***Patrica Thompson & Norine Whalen @ Royal Alexandra Hospital—1 patient***

Monthly Enrolment

December:	**8**	**patients**
January:	**16**	**patients**
February:	**10**	**patients to date**

In the month of January we had 13 sites screening patients and with our enrolment goal of 2 patients per site each month, we fell a bit short. Our goal in the month of February is to have at least 26 new patients enrolled in the study. If you have questions about inclusion or exclusion criteria, please do not hesitate to contact Daphne Mayer or Rupinder Dhaliwal.

Patients in ICU < 5 days

After reviewing the preliminary data entered thus far, we have noticed a higher then expected number of patients that received < 5 days of study supplements. These patients will not contribute to the overall analysis and we need to limit enrolment of such patients. We acknowledge that it is difficult to predict length of stay in the ICU as some outcomes are unavoidable (ex: death, withdrawal of care). From our review, it appears that many patients are being extubated and/or discharged from ICU within 5 days from ICU admission.

Please make sure that the Research Coordinator and the Site Investigator collaborate to determine if the patient's expected length of stay is for at least 5 days. If this is not the case and the patient meets inclusion criteria and no exclusion criteria that patient would be considered ***eligible but not randomized.***

How should this be entered into the eCR?. Once you get to the Pre-Randomization Form and you are asked *Did you obtain consent?*, select NO. You will be prompted for a reason the patient was not randomized. Select *other*, and enter *ICU LOS estimated < 5 days*.

Latex Free

The supplier of the study supplements, Fresenius Kabi, indicates that there is minimal chance the products are in contact with latex during the production process. The stoppers and caps used in the packaging of the supplements do not contain any natural latex compounds.

REDOXS© Study Contact Information

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Daily Data Exceptions: Blood Sugar

Daily data is collected for the 24 hr period according to your flowsheet. The exception to this requirement is blood sugar reading. In the Implementation Manual (page 31), we ask you to record the first blood sugar reading closet to 08:00. We would like to clarify that the reading can be 08:00 ± 6 hours. A reading between 02:00 and 14:00 is acceptable regardless of study day.

For example, for those of you NOT on a midnight to midnight flowsheet, if it is Day 10 and you have an available reading from Day 9 at 0400, you can enter this reading in for Day 10. If no reading is available from between 02:00 and 14:00, click N/A.

You do not need to worry about data already entered, but please apply this moving forward.

Other Vitamins, Minerals & Supplements: Please check your MVI's.

Mara Pavan, Pharmacist, St. Paul's Hospital noted that their routine MVI's have elevated levels of specific vitamins and minerals. Please remember, patients enrolled in REDOXS should not be on enteral formulas, parenteral solutions, or supplements that have elevated levels of glutamine, antioxidants or selenium (< 60 mcg), Vitamin A, C, E, beta carotene, zinc (< 5 mg) or arginine. If you have concerns, we invite the site Pharmacist to contact us to discuss further.

REMINDER: Daily data collection is based on your site's routine bloodwork. If you site does not have lab values for some of the fields, click Not Available (n/a). If the data is available, please collect and record in the eCRF.

Attention: Pharmacy

Patient Safety and Unblinding. Some sites have asked under what circumstances that unblinding would occur. The blind can only be broken in the event that the members of the Data Monitoring Committee, after reviewing the periodic safety reports, feel there is a safety concern. Since there is no antidote for the study nutrients, if the Site Investigator has concerns the nutrients can be stopped without unblinding. Therefore, if there is a request for unblinding of a specific patient, do NOT release the treatment allocation. Please have the Site Investigator contact CERU.

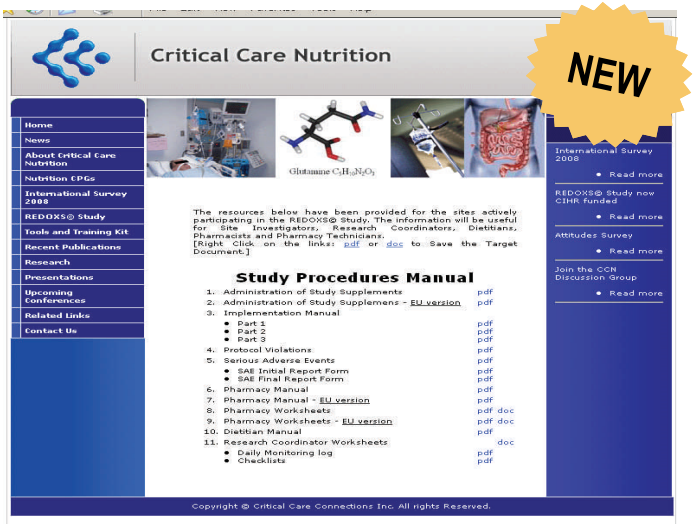
SF36 Survey for long stay patients

If the patient is still in ICU/hospital at 3 months or 6 months, the online version of the SF36 will not appear on the Patient Status page. In this event, the Research Coordinator will need to administer the survey manually and enter the data into the eCRF retrospectively, once discharge dates are known. A hardcopy of the SF36 can be found in the Implementation Manual (pg 87).

HAVE YOU HEARD?

REDOXS Study resources are now available on-line. Go to www.criticalcarenutrition.com click on The REDOXS© Study.

Select Resources; and choose from the REDOXS© Study Procedures Manual or REDOXS© Circulars and Bulletins. You can also download REDOXS© Training presentations to review.



Good Questions !!

Are we to measure/record gastric residual volumes if the patient is not being tube fed?
Yes, if the GRV is measured it should be recorded whether or not the patient is being tube fed. If the GRV is not measured, there is an option to select N/A on the eCRF.

Thanks to Pat Thompson, RAH, for the question

Does each patient have a Screening#, Enrollment# and CR#?
Yes. The Screening # is assigned once a patient is screened for the study. The Enrollment # is the number assigned at randomization. The CR# refers to the unique ID# that is assigned to each patient that is hospitalized....at KGH we call it the Chart Registry # (CR#). Please refer to page 12 of the Pharmacy Manual.

Thanks to Debi Snow, Capital Health, Halifax for the question.

Some patients are admitted initially to step-down ICU and later they are transferred to the ICU. Is the step-down ICU considered as an ICU stay and should the time in the step-down ICU be calculated as a ICU stay?

No, the ACTUAL time of admission to ICU is the ICU admission time. The 24 hour window starts from actual ICU admission, not the time that they were in the step-down ICU waiting for an ICU bed, even if they were ventilated in the step-down unit. For inclusion, the failures have to be present in the ICU, even if they started in the step down unit. The timing of the organ failure is the onset of organ failure. For example, for the P/F ratio, use the first P/F ratio <300 that was done on the ABG after they were ventilated.

Thanks to Boris Bojilov, Sunnybrook for the question.