

Clinical Evaluation Research Unit



The REDOXS[®] Study

REducing DEaths due to OXidative Stress

We have had a productive month and we are now actively enrolling at 9 sites across Canada. Thanks to our busy research coordinators, we have managed to enrol 28 patients within the last 12 weeks!

Research Team at CERU

Daren Heyland

Rupinder Dhaliwal

John Muscedere

Jennifer Korol

Enrolment Update

# patients enrolled	Site	# patients to go
10	Kingston General	1092
1	St. Joseph's Hamilton	
7	Ottawa General	
3	Ottawa Civic	
4	Sacre Coeur	
2	Maisonneuve-Rosemont	
1	Royal Alexandra	
28	TOTAL	

www.criticalcarenutrition.com
click on THE REDOXS[®] Study

New Resources on our website

Download the training power-point slides or how to accept cookies.

Coming soon.....revised study Procedures Manuals and other tools!

Are you checking for these daily?

Volumes of study supplements received

The volumes of the enteral and parenteral study supplements actually received must be checked **daily** using the checklist provided or your own worksheets. If the volumes received are less than 80-90% of the prescribed volumes, you must complete a protocol violation form and send it to CERU within 24 hrs of becoming aware of the violation. Refer to the Protocol Violation section of your Study Procedures Manual for more details. The protocol violation form can be downloaded from the REDOXS website after you log in.

Serious Adverse Events

Check for adverse events that are serious and unexpected on a **daily** basis using the checklists provided or your own worksheets. "Unexpected" means events that are NOT expected due to the progression of the underlying disease. Refer to the SAE section of your Study Procedures Manual

Worried about high doses of selenium?

Some of you may have read about a recent randomized controlled trial (Stranges et al Annals Internal Medicine Aug 2007) that concluded that long-term use of selenium supplements increased the risk of diabetes. Please note that the population in this study were outpatients seen in a dermatology clinic, not acute critically ill patients with organ failures. Please be prepared to address this should you be questioned about this by a family member at the time of obtaining consent.



Did you know?

We are extending our recruitment to non Canadian sites, including Europe, UK and USA?

Check web access *before* you enrol

Please see that you are able to access the web based data capture system **before** you enrol a patient.

Many users will need to have their internet access configured and this may take time and you may even need the IT staff at your site to reconfigure your settings. If you wait until you have an eligible patient, you may very well miss randomizing this patient.

As a reminder, passwords will only be issued by CERU once your regulatory paperwork and training has been completed.



Technical issues for web



613-484-3830

We would like to route all calls related to technical web issues through CERU before going to our IT support staff.

From now, please see that you contact Rupinder Dhaliwal (work # 613-549-6666 ext 3830 or cell # 613-484-3830) for any issues related to accessing the web or any technical problems instead of contacting the IT support staff.

Please make a note of this on your Study Contact list.



Any changes to the data capture?

We are always trying to make the data capture efficient, so, we are making a few changes.

Antibiotics

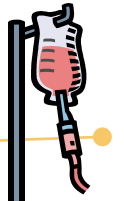
Effective now, you do NOT need to record changes in dose/route/frequency as a separate entry. EXCEPTION: If the antibiotics have been discontinued for more than 48 hrs and then restarted, then record this as a separate entry. For all other antibiotics record the start and stop date only.

Screening data for excluded patients

You need to enter screening data online for all patients meeting the inclusion criteria and an exclusion criteria. Effective now, for **excluded patients only**, you may use screening time as the time of organ failures instead of looking up precise dates and time of organ failures.

REDOXS[®] Product/Inventory

Please work with your nursing staff to ensure that the site pharmacy is notified **immediately** when the supplements are discontinued. This is essential for control of inventory and to avoid unnecessary workload by pharmacy staff. We are being notified by some of the pharmacists that the products are being wasted and this is creating extra work. Please see that your pharmacists are notified right away.



Good Questions!!

Are standard amounts of vitamins and minerals that are present in enteral and parenteral nutrition allowed?

Standard amounts of selenium (up to a maximum of 60 micrograms/day) and zinc (up to a maximum of 5 mg/day) that are already present in the parenteral solutions are allowed. Enteral or parenteral supplements/preparations that contain amounts of zinc (or selenium) higher than those above should not be allowed (eg. maternal supplements).

Thanks to Roger Autio and Monique Nicholson for asking this question.

Study Supplements orders for Study Day 1: The template orders were not very clear for Day 1. Can we not calculate the number of remaining hours and then divide the prescribed volumes over these hours instead of doubling the rate?

Yes! You may follow this method: Divide the prescribed volumes needed over the remaining hours in study day 1 and infuse the supplements at this rate. Study Day 2: infuse at regular rate i.e. 10 cc/hr parenteral and 20 cc/hr enteral. A revised order template will be available on our website soon.

Example: Patient admitted to ICU on July 23rd at 15:00 hrs, supplements started at 17:00 hrs and flowsheet runs from 07:00-07:00 hrs. Number of hours remaining in study day 1 (from 17:00 July 23rd to 06:59 July 24th) = 14 hours. Divide the prescribed volume of enteral supplements over the 14 hrs. For the enteral supplement, this is 480 mls/14 = 34 cc/hr until 07:00 hrs then at 07:00 hrs, restart at regular rate = 20 cc/hr. X 24 hrs for (study day 2). Similarly for parenteral.

Thanks to Norine Whalen/Pat Thompson for asking this question.

Eligibility: Is the patient that was admitted to ICU 2 weeks ago, was discharged and is now re-admitted to the ICU eligible?

Yes, but **only** if the organ failures are considered to be acute at this admission and are NOT a continuation from the previous admission to ICU. Also, remember that previous randomization in REDOXS means the patient is to be excluded at the next admission.

Thanks to Tracy McArdle for asking this question.