The REDOXS© Circular

June 2007 Issue # 1

Clinical Evaluation Research Unit

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

We are very pleased to bring to you the first issue of the newsletter for the REDOXS© Multicentre trial, the REDOXS Circular! Read on for an update of how the study is progressing and look out for important notices.

Staggered Start Dates

May 1st 2007	Kingston General started screening.
June 4th 2007	Ottawa General, Ottawa Civic, Sacre-Coeur started screening
Mid-end June 2007	St. Joseph's Hamilton, Royal Victoria, Maisonneuve-Rosemont, Royal Alexandria Edmonton and Charles LeMoyne to start screening
June- Sep 2007	Remaining sites expected to start.

Research Team at CERU

Daren Heyland

Rupinder Dhaliwal

John Muscedere

Jennifer Korol

www.criticalcarenutrition.com
click on THE REDOXS ©Study

Enrolment Update

Period	# patients enrolled	Site	# patients to go
May 1st - June 7th 2007	4	Kingston General	**1114**
June 4th -June 7th 2007	1	Ottawa Civic	
June 4th-June 11th 2007	1	Ottawa General	

Did you know?

We aim to have enrollment start at ALL sites by Fall 2007!

Worried about poor enrollment? Too many competing ICU studies?

Enrollment at Kingston General started on May 1st and other sites on June 4th and despite being involved in studies such as PROTECT (2 patients in Kingston were co-enrolled in PROTECT) and SUGAR (co-enrollment not allowed), to date a total of 6 patients have been enrolled within 6 weeks, illustrating that recruitment to REDOXS© is feasible even with competing and co-enrolling ICU studies!

Concerned about Antioxidants?

Some of you may be aware of the media attention that focused on the negative effects of antioxidants (Bjelakovic JAMA Feb 2007) We would like to point out that this report was based on studies that were conducted in patients with chronic illness, not critically ill patients and hence the results cannot be extrapolated to ICU patients.

Based on extensive work in critically ill patients, including our own research, antioxidants are very safe and there is no cause to worry. Please be prepared to address this should you be questioned about this by a family member at the time of obtaining consent.

Web Based Data Capture System

We have created a web based data capture system that is aimed at minimizing the workload of data entry.
It also includes a built-in logic check and ICU infection adjudication process. We hope that this will resolve the inefficiencies around the query resolution process.

Interested in getting a "feel" for the electronic data capture system before you start enrolling? If so, contact Rupinder Dhaliwal for access to our "test" site.

Training Sessions

We have been scheduling local training sessions for the research staff (site investigators, research coordinators,

pharmacists and dietitians) instead of one start up meeting to meet the individual site's needs. Where this is not possible, we have been contacting the research staff for one-to-one training over the phone.

Please let us know if your training needs have not been met. Look out for notices for training sessions in Vancouver, BC on June 29th and a session in Toronto in September 2007.

Ready to screen?

Do you have these study materials?

Once your regulatory paperwork has been submitted to us at CERU, you will need the following study materials before you are ready to screen/enrol:

- Study supplements to be shipped to your pharmacy and confirmation of receipt
- Study Binders (Study Procedures and Regulatory Binders)
- Poster, bottle openers, patient folders
- Daily checklists, pharmacy logs, study tools
- Username and passwords for research coordinators and pharmacists (to be assigned by the Project Leader upon receipt of completed and signed access logs).

If you are ready to screen patients but have not received these, please contact Rupinder Dhaliwal

"The most updated version of the Study Binder is June 1st 2007"

Good Questions!!

Timing of Consent: How much time do we have to obtain consent? Is it 24 hrs from ICU admission?

The patient must be screened AND consent needs to be obtained within 24 hrs from ICU admission since the supplements need to be started soon after admission to ICU. If it takes too long to obtain consent, this patient should not be not be randomized as there will be an unacceptable delay in starting study supplements.

Example: Patient gets admitted to ICU June 6th at 18:00 hrs and you screen the patient on June 7th at 11:00 hrs (screening is within 24 hrs from ICU admission) and he meets the eligibility criteria. If you are unable to obtain consent until June 8th at 09:00 hrs, do NOT randomize this patient . Remember: we do allow telephone consent. For reasons for not getting consent, choose OTHER and provide an explanation in the textbox.

Thanks to Boris Bojilov for asking this question.

Eligibility criteria: What about patients in which it is difficult to assess with precision the tolerance to enteral feeding? Should these patients be excluded if feeds are not expected to be tolerated?

No, these patients are eligible. It is understood that given the patient's organ failures, enteral feeds may not be tolerated or it may be difficult to ascertain how well the patient is going to tolerate enteral feeds. Either way, these patients should not be excluded unless they meet an exclusion criteria i.e. absolute contraindication to enteral nutrition. Remember, the study supplements are nutrients that are infused at low rates, they are very well absorbed even in patients that are not tolerating enteral nutrition.

Thanks to Tracy McArdle for asking this question.

Log in problem: After I log-in, I get a message saying "Session expired, log in again" and when I log in again, I still get the same message. I have tried changing my password but I still get the error message.

You may need to change your internet settings to allow cookies. Please see instructions that will be posted on our website after you log-in or you may contact Rupinder Dhaliwal for an electronic version of these instructions.

Thanks to Mary Jo Lewis for asking this question.