



Enrolment & Site News

Congratulations to Cheryl Ethier and the team at Mount Sinai Hospital in Toronto for enrolling your 1st REDOXS[®] patient!

Welcome to Susy Fleury, Nicole Godfrey and Megan Manning, the new research coordinator team at Kingston General Hospital. **Congratulations** on enrolling your 1st REDOXS[®] patient this month!

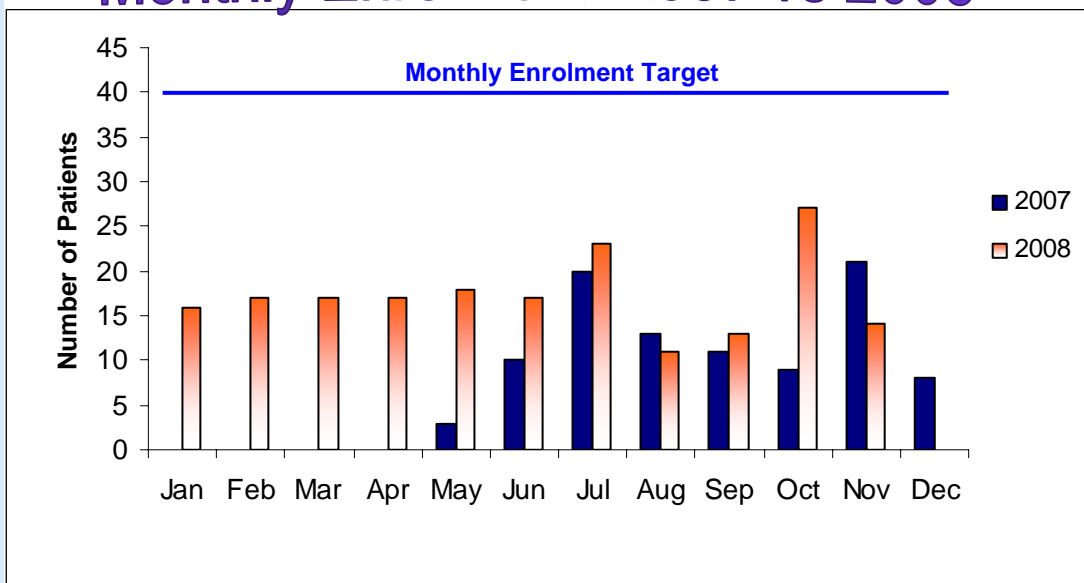


Welcome to our new US sites: the University of Colorado in Denver, Colorado and Miami Valley Hospital in Dayton, Ohio. We look forward to patient recruitment commencing at your sites in the coming weeks!

November Recruitment Update

14 patients were enrolled in the month of November and our target was 40 patients. Refer to the diagram to see how enrolment this year compares to last year. As of Dec 2007 we had 11 sites actively recruiting patients, though we have doubled the number of sites, our Nov enrolment fell below that of last year. We know you are all working hard, let's keep striving for our target of 40 patients/month!

Monthly Enrolment: 2007 vs 2008



835 patients to go!

NOTE: Patient recruitment was not initiated until May 2007

Child's Class C Liver Disease Classification

We recently received a question regarding how to define ascites in order to calculate the Modified Child-Pugh classification for the severity of liver disease. The classification grades ascites as **absent**, **slight** or **moderate**.

While one can tell if it is absent, determination of **slight** and **moderate** can be difficult. Since ultrasound is the main method to diagnose ascites, the radiologist report can be used to determine the amount of ascites present. If the ascites has been drained in the past, it should be considered **moderate**.

Refer to www.criticalcarenutrition.com in the resources section for more information.

Criteria	Points assigned		
	1	2	3
Total Bili			
Conventional	< 2 mg/dl	2.0 – 3.0 mg/dL	> 3 mg/dL
SI units	< 34 µmol/L	34 – 51 µmol/L	> 51 µmol/L
Serum Albumin			
Conventional	> 3.5 g/dL	2.8 – 3.5 g/dL	< 2.8 g/dL
SI units	> 35 g/L	28 – 35 g/L	< 28 g/L
Prothrombin time or INR	< 4 seconds	4 – 6 seconds	> 6 seconds
Ascites*	Absent	Slight	Moderate
Encephalopathy	None	Moderate	Severe

* Refer to ultrasound results. If ascites has been drained in the past, it should be considered Moderate.

Pharmacy Relabeling

For those sites affected, we wish to thank the Pharmacists for your perseverance and time dedicated towards ensuring the study products are properly relabelled.

Acute vs Documented History of Seizures

Are patients who have had an acute seizure requiring anticonvulsants eligible for the study?

If seizures occur in the ICU and the patient needs anticonvulsants and there is no documented history of seizures needing anticonvulsants prior to this illness, this patient is eligible. Patients with acute seizures requiring anticonvulsants are eligible yet patients with a history of seizures requiring anticonvulsants are an exclusion.

Thanks to Elizabeth Luzier & Angela Baer at, the University of Colorado for the question

Check the website for newly updated appendices to the Study Procedures Manual.

Frequency of Change of IV Tubing

At what frequency should we change the IV tubing for parenteral study supplements?

Once opened, the bag of parenteral study supplements is good for 24 hours only. You may change the IV tubing as per your hospital's standard protocol. This is done at varying frequencies depending on your institution (usually anywhere from 24-72 hours). For further detail, refer to the Administration of Study Supplements Manual, page 6.

Thanks to Cheryl Ethier, Mount Sinai Hospital for the question

Holiday Coverage

Please note CERU observes a shutdown period from Dec 25th to Jan 2nd.

During this time please call (613) 484-3830 for urgent study related issues.

Good Questions !!

When a patient is extubated, receiving parenteral nutrition and eating a little bit, do we need to calculate the amount of calories and proteins from oral feeding?

No need to calculate calories and protein from oral feeding. We only need the calories and protein for parenteral and enteral nutrition.

We had a patient that was discharged from the ICU to the floor after being on study supplements for 2 weeks.

Our pharmacist was asking if study supplements could be continued on the floor as long as the site investigator was agreeable?

If a patient is discharged to the floor before the patient has received 5 days of study supplements then study supplements would be continued on the floor to achieve the 5 days. Given the scenario above, since the patient has already received 5 days of study supplements they should not be given study supplements on the floor, the duration cannot be extended at the discretion of the Site Investigator.

Thanks to Dr. Lauzier, Hopital Enfant-Jesus for the questions



HAPPY HOLIDAYS

We here at CERU consider ourselves very fortunate to be able to work with such an incredible group of dedicated professionals. On behalf of Dr. Heyland and the rest of the team at CERU we want to thank each of you for your continued support and efforts towards ensuring the REDOXS® Study is a success.

We wish you all a happy holiday season full of family, friends and fun!



CERU RESEARCH TEAM

Daren Heyland
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Monthly Reports

As a result of the Project Leader transition we put a hold on monthly reports for the months of October and November. We plan to resume the monthly reports in the New Year. Look for the December 2008 report in early January 2009.