



Enrolment Update as of December 31, 2008

Sites Currently Enrolling	December	Total
Kingston General	2	45
St. Joseph's Healthcare, Hamilton	2	19
Ottawa General	4	61
Ottawa Civic	-	27
Vancouver General	-	12
Sacre Coeur, Montreal	2	34
Maisonneuve-Rosemont, Montreal	-	11
Royal Alexandra, Edmonton	1	13
Grey Nun's, Edmonton	-	9
Victoria General	1	3
London Health Science Centre	-	10
Health Science Centre, Winnipeg	-	7
Queen Elizabeth II HCS (Halifax)	-	5
Sunnybrook, Toronto	2	2
St. Paul's, Vancouver	1	5
L'Enfant Jesus, Quebec City	-	10
Leige, Belgium	-	1
CHUV, Switzerland	-	7
Royal Jubilee Hospital, Victoria, BC	-	3
UZ Brussel	2	2
Mount Sinai, Toronto	1	2
University of Colorado	1	1
304 + 80 (from pilot) = 384 total		

816 patients to go!

With 384 patients enrolled to date, let's strive to surpass the 400 patient mark in January!!!

With 19 patients enrolled in December, we more than doubled the number of enrollments compared to Dec 2007!

Congratulations to **Godlieve Opdenacker** at UZ Brussels, Belgium for enrolling your first 2 patients!

Congratulations **Elizabeth Luzier** at the University of Colorado for enrolling your first patient and the first US patient into the study!

Congratulations **Karen Code** at Sunnybrook Health Sciences Centre, Toronto for enrolling your first 2 patients!

Welcome to our newest sites from the US, the **University of Vermont** and the **University of Louisville**.

CERU RESEARCH TEAM

Daren Heyland
John Muscedere
Suzanne Biro

Rupinder Dhaliwal
Janet Overvelde
Jennifer Korol

Defining Mechanical Ventilation

If a patient is extubated but on BiPAP, is this considered mechanical ventilation for the purpose of the study?

We define mechanical ventilation as intubation with mechanical ventilation or tracheostomy with mechanical ventilation. This includes any positive pressure delivered via endotracheal tube or a tracheostomy. This does not refer to non-invasive methods of ventilation such as BiPAP or mask-CPAP unless non-invasive ventilation (e.g. BiPAP, CPAP) is delivered through a tracheostomy (if latter, then considered invasive mechanical ventilation).

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

Monitoring Ammonia Levels in Patients with Unexpected Neurological Symptoms

Upon review of the SAEs so far reported to the Methods Centre, we would like to remind folks that if your REDOXS patient develops an unexpected neurological symptom (such as seizures or hepatic encephalopathy), please note that we encourage that serum ammonia levels be measured, to help with sorting out the underlying cause of those events. Furthermore, such events, if not expected due to the progression of underlying disease, are to be reported to the Methods Centre within 24 hours of becoming aware of the event as they would be considered SAEs.



REDOXS Honour Roll 2008



The Honour Roll is a way for the REDOXS® Study project team to recognize and acknowledge the top performing sites of the year. Drum roll please....

Top Enrollers

1. The Ottawa Hospital—General Campus, Ottawa, ON
2. Kingston General Hospital, Kingston, ON
3. The Ottawa Hospital—Civic Campus, Ottawa, ON
4. Hôpital Sacre-Coeur, Montreal, QC
5. St. Joseph's Healthcare, Hamilton, ON
6. Hôpital Enfant-Jesus, Quebec City, QC
7. Vancouver General Hospital, Vancouver, BC
8. Grey Nun's Community Hospital, Edmonton, AB
9. London Health Sciences Centre, London, ON
10. Royal Alexandra Hospital, Montreal, QC

The Team at Ottawa General:

- | | |
|-----------------------------------|------------------------------|
| Dr. Gwynne Jones | Denise Frechette, Dietitian |
| Dr. Redouane Bouali | Alison Simpson, Dietitian |
| Tracy McArdle, Study Coordinator | Ann Marie Dugall, Pharmacist |
| Irene Watpool, Study Coordinator | Susan Feltzer, Pharmacist |
| Claude Gaudert, Study Coordinator | |

Congratulations to the team at Ottawa General for being the Top Enroller of 2008!!!

Stay tuned for the profile of this team to be found on www.criticalcarenutrition.com next month.

Sites with the Highest Study Supplement Compliance

Enteral Supplements

1. Vancouver General Hospital, Vancouver, BC
2. Royal Alexandra Hospital, Edmonton, AB
3. Grey Nun's Community Hospital, Edmonton, AB
4. London Health Sciences Centre, London, ON
5. The Ottawa Hospital—Civic Campus, Ottawa, ON

Parenteral Supplements

The following sites reached the best achievable level of compliance, 100%:

- Kingston General Hospital, Kingston, ON
- Royal Alexandra Hospital, Edmonton, AB
- Grey Nun's Community Hospital, Edmonton, AB
- London Health Sciences Centre, London, ON
- Montreal General Hospital, Montreal, QC

On behalf of Dr. Heyland and the rest of the REDOXS® Study project team we thank you and offer our congratulations on making the REDOXS® Honour Roll 2008. We look forward to watching the competition heat up for 2009 as we activate new sites in the US and Europe!

Tiger Tube™ - Small Bowel Feeding

Given the severity of illness in patients enrolled to REDOXS®, there may be a reluctance to start the enteral study supplements early or continue with them in the face of high gastric residual volumes.

Feeding via the small bowel may be advantageous in patients with persistent high gastric residuals. We are willing to provide you with self-advancing naso-jejunal tubes from COOK Medical. These tubes are called Tiger Tubes™ Frictional Nasal Jejunal Feeding tubes and they are considered to be easy to place.

If you are interested in trying the Tiger™ Tubes in your REDOXS patients, COOK Medical has agreed to provide 5 tubes free of charge.

Please contact the latest COOK representative Debbie Christie if you are interested: Debbie.christie@cookmedical.com, tel: (416) 716-6430. Please refer to the Study Bulletin: Small Bowel Feeding (Sept 26/07) for more details regarding these tubes, including contraindications.

REGULATORY DOCUMENT UPDATES

We need to fill in the gaps for the regulatory documentation we are missing in our Methods Centre files. In the coming weeks you may receive request from us to forward training records, CVs, ethics acknowledgments and other regulatory documents. We thank you for your cooperation to ensure these files are complete.

Coming soon...

We will be starting our data cleaning processes at CERU in March. What this means is sites may begin to see data queries. More information to follow in March.

? ? ? Questions or Comments ? ? ?

Email Janet Overvelde @ overvelj@kgh.kari.net