

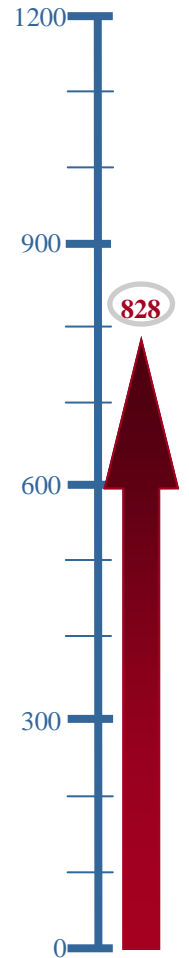
THE REDOX[®] CIRCULAR

Data current to 30-June-2010

| Site # | Institution | Jun | Cumulative |
|--------|-----------------------|-----|------------|
| 1 | Kingston General | 1 | 75 |
| 2 | St. Joseph Healthcare | 2 | 56 |
| 3 | Ottawa General | 3 | 145 |
| 4 | Ottawa Civic | 1 | 51 |
| 5 | Vancouver General | - | 20 |
| 6 | Sacre-Coeur | 4 | 69 |
| 7 | Maisonneuve-Rosemont | - | 15 |
| 8 | Royal Victoria | 1 | 12 |
| 9 | Royal Alexandra | 1 | 24 |
| 11 | Grey Nun's | - | 15 |
| 13 | Victoria General | - | 6 |
| 14 | London HSC | 2 | 17 |
| 16 | Capital Health, QEII | - | 17 |
| 19 | Montreal General | - | 18 |
| 20 | L'Enfant Jesus | - | 26 |
| 21 | Liege, Belgium | - | 8 |
| 22 | CHUV, Switzerland | - | 11 |
| 23 | Royal Jubilee | - | 9 |
| 25 | Mount Sinai | 1 | 36 |
| 26 | U of Colorado | - | 19 |

| Site # | Institution | Jun | Cumulative |
|------------------------------------|--------------------------|----------------------|------------|
| 27 | Miami Valley, Ohio | 1 | 9 |
| 28 | Fletcher Allen, Vermont | - | 9 |
| 30 | U of Louisville | 3 | 18 |
| 31 | U of Texas | 1 | 7 |
| 32 | University Hospital | - | 7 |
| 33 | Laval | - | 10 |
| 34 | Emory University | - | - |
| 35 | Kiel, Germany | - | 3 |
| 36 | Lubeck, Germany | Site closing | |
| 37 | Greifswald, Germany | - | 8 |
| 38 | Hamburg-Altona, Germany | - | 4 |
| 39 | Jewish Hospital | 2 | 3 |
| 40 | Atlanticare | 2 | 3 |
| 41 | Hershey Medical Center | - | - |
| | Intermountain Healthcare | Starting soon | |
| 43 | Mayo Clinic, Arizona | - | - |
| *number patients from closed sites | | | 18 |
| number patients enrolled in pilot | | | 80 |
| TOTALS | | 25 | 828 |

ENROLMENT COUNTDOWN



Enrollment News

- ★ Félicitations Patrice Deroy and Huber Simard at Sacre-Coeur for enrolling 4 patients in June! Outstanding job!
- ★ The teams at Ottawa General and University of Louisville have done a fantastic job this month, each site has enrolled 3 patients!
- ★ We would also like to acknowledge the efforts of the following sites for enrolling 2 patients each in June: St. Joseph's Healthcare, London HSC, Jewish Hospital and Atlanticare.
- ★ Thank you to the following sites for enrolling 1 patient in June: Kingston General, Ottawa Civic, Royal Victoria, Royal Alexandra, Mt Sinai, Miami Valley and the University of Texas.

Sample Size

At the recent CCCTG meeting in PEI, Dr. Heyland raised the issue of whether the study sample size should be inflated to make up for patients that did not receive at least 5 days of study supplements (non responders) and to account for a smaller treatment effect because of recent negative glutamine and antioxidant trials. After much discussion at the CCCTG meeting regarding such patients and the new evidence on glutamine and antioxidants, the decision was made not to change the sample size and to continue with a total goal of 1200 patients.

Suspected, Unexpected SAE Report

Recently a suspected, unexpected SAE (SUSAR) was reported from one of our Canadian sites. The event was Pericarditis and was assessed as having a possible relationship to study supplements. In accordance with regulatory regulations an initial SUSAR has been forwarded to all appropriate study stake holders.

Dr. Heyland has reviewed this report and made the following commentary:

The cause of the pericardial effusion could be related to underlying disease (sepsis, renal failure). Impossible to know if 'caused' by study nutrients but for sure the study nutrients could have contributed to the uremia so I understand how it could be 'possibly related.' There are no other such reports in our trial and thus, I don't feel this represents a significant change in risk.

A follow-up report will be sent to all sites and stakeholders once the information has been obtained. Research sites are reminded to submit this initial report to their local ethics committee.



Strategies & Initiatives to Enhance REDOX[®] Enrollments: Feedback from a Top Recruiting Site

A REDOX[®] meeting was recently conducted in PEI, Canada (in conjunction with the CCCTG meeting), items discussed at this meeting included an enrollment update and review the Periodic Reports derived from the first 600 patients randomized. During this session the Team at Ottawa General was kind enough to share some of the strategies and initiatives they find enhance recruitment at their centre.

- ◆ The research team is a resource for anyone looking to conduct research. They will assist researchers in all aspects of research such as REB submissions, seeking funding and enrolling patients. This 'pay it forward' attitude creates an environment open to study enrollments.
- ◆ The research team sponsors team building events and lunch & learns with the ICU clinician groups (e.g. nursing)
- ◆ The research team meets with residents and fellows monthly regarding the various studies ongoing in the ICU.
- ◆ The research team provides funding for Dietitians to attending conferences
- ◆ Perform telephone consents

These strategies most notably create an environment which fosters research which certainly pays off as evidenced by REDOX[®] enrollments!

~A special thanks to Tracy McArdle, Irene Watpool and Dr. Gwynne Jones

REDOXS Reminders On the day of randomization we advise sites to double up the rate of study supplements in attempts to ensure a full dose is received on this study day. Sites have expressed that this is sometimes difficult, particularly regarding the enteral study supplements, when a patient may require multiple surgeries within the first couple of days of enrollment.

The decision to feed a patient is up to the surgeons, Dr. Heyland encourages coordinators to relay to the surgeons that antioxidants, glutamine and saline are beneficial to the gut in these circumstances. It is acceptable for a patient to maintain the enteral study supplements at a rate of 20 mL/hr (½ the prescribed volume) on the day of randomization to keep surgeons comfortable. Additionally, if necessary, we allow for a short delay from 8-12 hrs in the initiation of enteral study supplements.

If patients are intolerant to feeds or the surgeon is hesitant to begin feeding due to high gastric residual volumes, the site may consider using a small bowel feeding tube such as the Tiger Tube, as they are an effective way of feeding the bowel distal to the jejunum, thereby eliminating the concern regarding intolerance and residuals.



THANK YOU Pharmacists for your attention to the recently instituted enteral study supplement re-labeling process. Re-labeling has been completed at the majority of our sites well over a month before the deadline!

Sincerely, Maureen Dansereau, Project Assistant

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