THE RE-*ENERGIZE* STUDY

The RE-ENERGIZE Rag

Volume #2 **August 2016**

We have been busy over the last few months initiating over 70 sites in Canada, the U.S., and Europe. To help with the coordination of the trial in Europe, we have partnered with Dr. Michael Chourdakis and his colleague, Eirini Kasapidou, from Greece. They recently visited us in Kingston to receive training and exchange ideas.

The RE-ENERGIZE Team(from left to right): Maureen Dansereau (Project Leader), Dr. Michael Chourdakis (European Partner), Janet Overvelde (CERU Operations Manager) , Dr. Daren Heyland (Sponsor), Tammy McQuade (Project Assistant), and Eirini Kasapidou (European Project Leader).

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We have 241 patients enrolled to date!
Only 2,459 to go!!

- **We need all hands on deck to reach our recruitment goal over the next 4 years.**
- **Please do what you can to move the start up process forward as fast as possible and then, once activated, do what you can to enroll as many patients as possible. Let's prove to ourselves that we can do mortality-based burn research.**

ACTIVATED SITES and ENROLLMENTS

Centre	Randomized to date
Mercy Hospital St. Louis, St. Louis, MO	6
Joseph M. Still RF, Augusta, GA	6
Hopital l'Enfant-Jesus,Quebec, QC	5
Harborview Medical Centre, WA	5
University of Iowa, Iowa City, IA	4
Univeristy of Colorada, Denver, CO	4
Wake-Forest University Health Sciences , Winston, Salem NC	3
University of Southern California, Los Angles, CA	2
Ross Tilley Burn Centre, Toronto, ON	1
Columbia, St. Mary's Hospital, Milwaukee, WI	1
Vancouver General Hospital, Vancouver, BC	
UF Health at Shand's Hospital, Gainesville, FL	
Saint Elizabeth Medical Centre, Lincoln, Nebraska	
Pilot Study	204
TOTAL	**241**

A few reminders:

- Access study material on our website at criticalcarenutrition.com
- Send us your ICF to review before submitting it to ethics.

Bonus: The RE-ENERGIZE video presented at the ABA conference is also on the website.

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UPDATES

We had a great RE-ENERGIZE meeting during The ABA Conference. Our discussions resulted in a few changes to data collection.

1) Daily Nutrition

- We are not collecting Calories from IV Fluids containing Glucose
- We are collecting adequacy of intake via the oral route expressed as a percentage. Every study day the patient receives oral nutrition, even if they are also receiving EN and/or PN, record the percent adequacy received via the oral route as one of the following:
  - 0- 24% of prescribed intake
  - 25 - 49% of prescribed intake
  - 50 - 74% of prescribed intake
  - > 75% of prescribed intake
  - Unknown

2) Concomitant Medications

- Beta-Blockers
  - We are collecting all beta blockers given, including dose, units, and route.
  - Propranolol is now being collected under the 'Beta-Blockers' question instead of as a stand-alone.

We have also added the collection of Heart Rate, both highest and lowest of the day, for each patient every day they are on study from ACU admit to 10 days post last graft, discharge, or ACU admission

NOTE: This data is entered on the concomitant medication form

3) Acute Care Unit (ACU) re-Admission

We are now collecting ACU readmission for this study. Please enter the ACU re-admission dates and times for each patient until 3 months post ACU admission to a maximum of 5 admissions.

Please send ALL of your questions, we are happy to provide answers!

Recording Final Assessment of %TBSA Grafting:

Record the actual %TBSA that required grafting, not a percentage of the Initial area expected to require grafting.

Example:
Initial Grafting Assessment expected to require grafting = 15% TBSA
Final Grafting Assessment - area that actually required grafting = 15% TBSA

Record the Final Grafting Assessment as 15% TBSA required grafting.

*Do **not** record the final assessment as 100% TBSA*

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FAQ Corner

We receive lots of questions. Each month, we will share a few with all of you here.

Question: Is a patient eligible 7 days after the burn injury?
Answer: If it has been more then 24 hours from injury, do not include the patient in the study. While the patient is not explicitly excluded per the eligibility criteria, early intervention post burn is key to glutamine efficacy.

Question: Do we record Lactate values from arterial or venous blood draws?
Answer: Collect Lactate data from arterial blood samples only. For the purposes of this study, only collect Lactate on mechanically ventilated patients.

Questions are always welcomed!

PHARMACY CORNER Q & A:

Question: Is the daily dose of glutamine or placebo rounded to adjust to the packet size?
Answer: Dosing is rounded to the nearest 5g to accommodate dispensing in 5g packets.
Question: Do we destroy expired product onsite, or return it?
Answer: Once you have confirmed with the CERU study team that the product expiry is not going to be extended, please destroy the product per your local pharmacy standard procedures.
Question: Do we adjust the dose of study medication when the patient's weight changes?
Answer: The site investigator or research coordinator will inform you if the patient's dosing weight changes. Dosing is based on the patient's pre-burn dry weight and should not be changed unless the weight change is significant enough that the clinical team changes the dosing weight for the other medications the patient is receiving. Example: lower extremity amputation

Please remember only pharmacy staff are unblinded.

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