THE RE-*ENERGIZE* STUDY

THE RE-ENERGIZE RAG

Dr. Heyland and Colleagues at the European Burn Conference

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August Enrollment: 11 Patients
September Enrollment: 20 Patients
5 Active Sites in Europe

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Goal: 1 Patient/Site/Month	ACTIVATED SITES and ENROLLMENTS		
INSTITUTION and Location	August 2017	September 2017	To Date
Oregon Burn Center* (21)	4	0	33
University of Colorado Denver* (26)	1	2	37
Ross Tilley Burn Centre, Sunnybrook* (13)	1	0	29
Hopital l'Enfant-Jésus	1	2	21
AHN West Penn Burn Center	1	1	12
UT Southwestern Medical Center	1	0	9
University of California, Davis	1	1	4
RWTH Aachen University, Aachen	1	0	1
Joseph M Still RF, Doctors Hospital* (37)	0	1	52
University of Iowa* (47)	0	1	63
Mercy Hospital St. Louis* (31)	0	0	43
University of Southern California	0	0	8
Wake Forest University Health Sciences	0	0	9
Harborview Medical Center - Seattle	0	0	14
UF Health at Shands Hospital	0	0	1
Columbia - St. Mary's Hospital	0	2	10
Foothills Hospital	0	0	4
Tampa General Hospital-USF	0	1	2
CHI Health St. Elizabeth	0	0	2
Akron Children's Hospital	0	0	4
MedStar Health Research Institute	0	1	4
The Ohio State University Medical Center	0	0	3
Firefighters' Regional Burn Center TN * (14)	0	0	15
Bridgeport Hospital	0	0	4
Hamilton General Hospital	0	1	4
Hotel-Dieu de Montreal - CHUM	0	2	4
University of Texas Health Science Centre	0	1	2
Arizona Burn Center - U of Arizona	0	2	6
JBSA Fort Sam Houston	0	0	2
Ghent University Hospital	0	0	0
University of Nebraska	0	0	2
Hospital Universitario La Fe, Valencia	0	1	4
Queen Elizabeth Hospital Birmingham	0	0	0
University Hospital of Liège	1	1	2
Chelsea and Westminster Hospital	0	0	0
Pilot Study additional enrollments*		0	15
*(pilot + definitive)TOTAL	11	20	423

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FAQ Corner

Keep your questions coming so we can all continue to learn and grow together!

Question: If a patient develops renal failure while on the study treatment, should we stop the study medication?

Answer: The development of renal failure is NOT a contraindication to glutamine. If the patient is receiving dialysis, they will lose glutamine in the dialysate the glutamine should continue. If the patient is not being dialyzed, many units continue glutamine regardless. If the clinical team is not comfortable with the patient's urea levels, the study medication may be held for a day or 2 until the urea levels improve or dialysis is started. If the study medication is held, it needs to be restarted as soon as possible and any missed doses made up.

Question: - If we stop the study medication early, should we take the patient off the study?

Answer: - Do not take the patient off study. This is an 'intent-to-treat' study. All randomized patients should remain in the study even if the study medication is stopped**. Continue on with data collection.**

Question: When a patient's weight is in the middle of a range: 52.5 kg, should we round the weight for dosing?

Answer: Yes, please round down when the decimal is **.4** and round up at **.5**. If it is in relation to the study IP, the CRS calculates the dose automatically when the patient's height and weight are entered. The only exception would be if the patients dosing weight changed during the course of the study.

Question: Does urine output have to be collected hourly?

Answer: No, we do not ask for hourly urine output, we ask for the volume range of urine output from the first 24 hours after ACU admission to be indicated by selecting one of the following:
This is for calculation of a modified SOFA score.

- ❑ < 200 mL/day
- ❑ 200 - 499 mL/day
- ❑ ≥ 500 mL/day
- ❑ Not Available

Question: Is past history of renal transplant an exclusion criteria for the study ?

Answer: No, history of renal transplant is not an exclusion criteria for this study.

Question: If more than 100% of study product is given in a day to make up for missed doses the previous day, is it a protocol violation (IP overdose)?

Answer: No, there is no concern of IP overdose for this study. This question has been posed to the Steering Committee more than once. The amount of IP given to make up missed doses is limited to double the scheduled does in order to maximize absorption. If "excess" glutamine is received, it will simply be eliminated through the bowel.

Question: Do we have to return "extra-bags" of the IP product to our pharmacy for future patients ?
Answer: You and your pharmacist should follow the standard procedure for any dispensed or unused medication at your facility. We do not recommend re-dispensing the study product as the storage conditions of the IP are not documented after the IP leaves the pharmacy. However, the IP needs to be returned to the pharmacy for accountability. If the pharmacy team has questions, please contact our Central Pharmacy Depot Manager, Chris Gray (contact info on the last page of this newsletter).

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IMPORTANT NOTES

Overall

- Keep up the hard work that keeps us steadily moving forward. We appreciate each of you!!!

Reminders

- **Enter ALL patients who meet the Inclusion Criteria into the CRS:**

Inclusion Criteria Present	Exclusion Criteria Present	Informed Consent Obtained	Enter into CRS	Comments
✗	✗	Do not approach for consent as inclusion criteria not met	✗	
✓	✓	Do not approach for consent as exclusion criteria met	✓	Ineligible patient
✓	✗	✓	✓	Randomized patient
✓	✗	✗	✓	Eligible but not randomized patient

Some of you are only entering randomized patients into the CRS. Please take the time each month to enter the patients you have screened, but were not randomized. Thank you!

Budget Amendments

- The revised, increased per patient payment schedule went into effect on the 21st of March, 2017. Even if you have not yet accepted the increased budget via email acknowledgement or do not have an agreement amendment executed, all patients enrolled on or after March 21st, 2017 will be paid according to the increased payment schedule tiers.

CRS

Some of you have reported issues with the Pre-Randomization form not loading in the CRS when using Internet Explorer. If you are able to use a different browser, such as Google Chrome, Mozilla Firefox, or Apple Safari you will not have any difficulties with the CRS.

Protocol Amendment (27-March-2017)

- Those of you who do not yet have approval of the amended protocol, please push this forward so you can begin enrolling patients per the revised Inclusion Criteria. If you have questions or need information from us, just ask.

Pharmacy Reminder: Order product well in advance to allow time for delays when the product is in transit! We cannot guarantee short notice orders will be delivered in a timely manner.

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