

RE-ENERGIZE EUROPEAN TEAM

Dr. Heyland and our European Partners

October 2016 at the

RE-ENERGIZE training in Germany

Aachen University
is our most recently activated site!



July 2017 Enrollment



Total: 26 patients

**Highest Monthly
Enrollment to Date**

First Patient Enrolled in Belgium

Congratulations to the team at

University Hospital of Liège!



ACTIVATED SITES and ENROLLMENTS

INSTITUTION and Location	July 2017	Randomized to date
Ross Tilley Burn Centre, Sunnybrook, Toronto, ON*	3	30
Oregon Burn Center, Portland, OR*	3	28
University of California-Davis, Sacramento, CA	2	2
Bridgeport Hospital, Bridgeport, CT	2	4
Hamilton General Hospital, Hamilton, ON	2	3
UT Southwestern Medical Center, Dallas, TX	2	6
Columbia - St. Mary's Hospital, Milwaukee, WI	2	8
Foothills Medical Centre, Calgary, AB	1	4
Hotel-Dieu de Montreal – CHUM, Montreal, QC	1	3
JBSA Fort Sam Houston, San Antonio, TX	1	2
University of Colorado Denver, Denver, CO *	1	34
Hospital Universitario La Fe, Valencia, Spain	1	3
Hôpital l'Enfant-Jésus, Quebec, QC	1	18
University of Iowa, Iowa City, IA *	1	64
Mercy Hospital St. Louis, St. Louis, MO*	1	44
University Hospital of Liège	1	1
Harborview Medical Center, Seattle, WA	1	14
Arizona Burn Center - U of Arizona, Phoenix, AZ		4
Wake Forest University Health Sciences, Winston-Salem, NC		9
AHN West Penn Burn Center, Pittsburgh, PA		10
University of Nebraska Medical Center, Omaha, NE		2
Akron Children's Hospital, Akron, OH		4
MedStar Health Research Institute, Washington, D.C.		3
University of Southern California, Los Angeles, CA		8
CHI Health St. Elizabeth, Lincoln, NE		2
Joseph M Still RF, Doctors Hospital, Augusta, GA *		51
UF Health at Shands Hospital, Gainesville, FL		1
University of Texas Health Science Centre, Houston, TX		1
The Ohio State University Medical Center, Columbus, OH		3
Tampa General Hospital/USF, Tampa, FL		1
Firefighters' Regional Burn Center, Memphis, TN*		15
Pilot Study additional enrollments*		11
*(pilot + definitive)TOTAL	26	392

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

Question: Now that our patient is off of the study medication, may we give glutamine enriched formulas?

Answer: No, once randomized the patient may not receive Arginine or Glutamine enriched formulas until after the 6 month survival status has been obtained. The primary outcome of this study is 6 Month Mortality. Giving the patient glutamine during that 6 month period would contaminate the study results.

Question: Is it safe to enroll severe diabetic patients in the study?

Answer: Yes, it is safe for diabetic patients to receive the study intervention. Glutamine enhances insulin sensitivity and maltodextrin provides a trivial amount of calories (3.78 kcal/g), which is not of concern in relation to the total prescribed kcal/day for these patients.

Question: When screening a patient exposed to explosives such as fireworks, do we need to differentiate between surgical needs due to tissue damage from explosives versus burn injury?

Answer: No, the injury should be assessed as a whole.

Question: When entering propofol volume received, does it matter what strength was given?

Answer: No, the strength does not matter. We collect the volume of propofol to calculate calories received from propofol. The calories are in the emulsion not in the propofol, so the strength does not matter. Each mL of propofol contains 1.1 kcal not matter the strength.

Question: In REDCap, is the Concomitant Medications form only completed when the patient has received both Oxandrolone and Beta Blockers?

Answer: No, the form should be completed if the patient received either oxandrolone or a beta blocker. Complete the form by answering 'Yes' to the question "*Were Concomitant medications received today?*" and then answer the oxandrolone and beta blocker questions individually.

Question: When making up missed doses, what is double the dose if a patient gets a different number of packets at different times?

Ex. a patient gets 10 packets a day, which are scheduled as follows: 2, 1, 2, 2, 1, 2 packets. In this case, would a double dose be 3 packets or 4 packets?

Answer: A double dose would be 4 packets (2 + 2 packets). There is no safety concern when administering double doses. The limit of a double dose and/or doses at least one hour apart is to maximize absorption of the study medication.

Question: Do we need to record more than 12 days of nutrition data in REDCap?

Answer: No, we are only collecting nutrition data of the first 12 days after ACU admission. Refer to the CRF worksheets (pages 25-29). If you need a copy of the newest version, let us know.

IMPORTANT NOTES

Overall

- This was a best enrollment month yet! Keep up the hard work that keeps us steadily study 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)

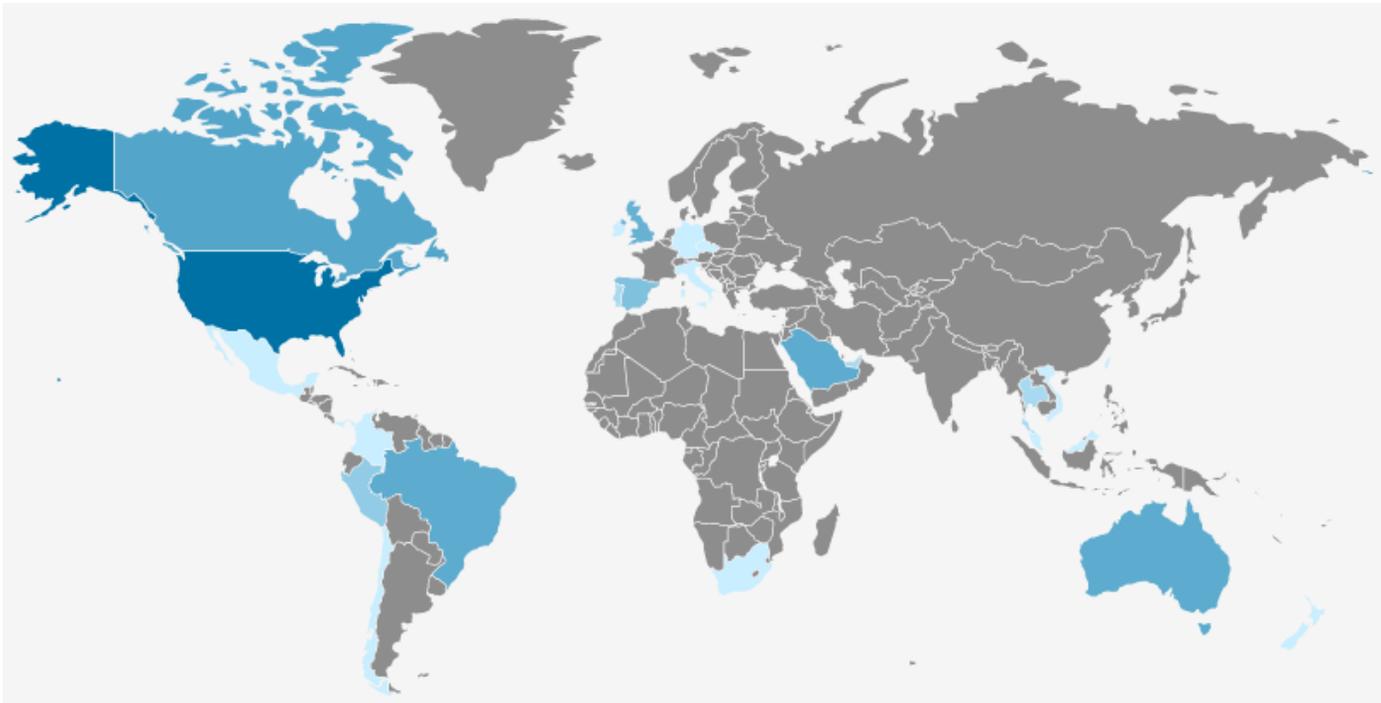
- Those of you who do not yet have approval of the amended protocol, please push this forward so you can begin enrolling patients per the revised Inclusion Criteria. If you have questions or need information from us, just ask.

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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Real-Time-CNN-Visitor-Map

Worldwide visits to the CNN website increased this month



**Dear Colleagues, for more RE-ENERGIZE study tools
please visit our website**

<http://www.criticalcarenutrition.com/>

RE-EN Study Tools:

- **Manuals and Case Reports Forms**
 - **Tools and Logs**
 - **Training Modules**
 - **Questionnaires**