THE RE-*ENERGIZE* STUDY

THE RE-ENERGIZE RAG

Volume # 6 **June 2017**

RE-ENERGIZE UK TEAM

Dr. Heyland and our European Partners with team members from our UK sites at the RE-ENERGIZE training conference in London on May 2nd, 2017.

May 2017 Enrollment

Total: 17 subjects

Highest Monthly Enrollment to Date

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Goal: 1 Patient/Site/Month

ACTIVATED SITES and ENROLLMENTS

INSTITUTION and Location	February – May 2017	Randomized to date
Hôpital l'Enfant-Jésus, Quebec, QC	6	16
Ross Tilley Burn Centre, Sunnybrook, Toronto, ON*	6	23
University of Iowa, Iowa City, IA *	3	62
Mercy Hospital St. Louis, St. Louis, MO*	3	43
Wake Forest University Health Sciences, Winston-Salem, NC	3	8
Harborview Medical Center, Seattle, WA	3	12
Columbia - St. Mary's Hospital, Milwaukee, WI	3	6
AHN West Penn Burn Center, Pittsburgh, PA	3	9
MedStar Health Research Institute, Washington, D.C.	3	3
Oregon Burn Center, Portland, OR*	3	24
University of Southern California, Los Angeles, CA	2	8
CHI Health St. Elizabeth, Lincoln, NE	2	2
Bridgeport Hospital, Bridgeport, CT	2	2
Hotel-Dieu de Montreal – CHUM, Montreal, QC	2	2
Arizona Burn Center - U of Arizona, Phoenix, AZ	2	2
University of Colorado Denver, Denver, CO *	1	31
Joseph M Still RF, Doctors Hospital, Augusta, GA *	1	51
UF Health at Shands Hospital, Gainesville, FL	1	1
Hamilton General Hospital, Hamilton, ON	1	1
UT Southwestern Medical Center, Dallas, TX	1	1
University of Texas Health Science Centre, Houston, TX	1	1
JBSA Fort Sam Houston, San Antonio, TX	1	1
University of Nebraska Medical Center, Omaha, NE	1	1
Foothills Medical Centre, Calgary, AB		3
Akron Children's Hospital, Akron, OH		3
The Ohio State University Medical Center, Columbus, OH		3
Tampa General Hospital/USF, Tampa, FL		1
Firefighters' Regional Burn Center, Memphis, TN*		15
Hospital Universitario La Fe, Valencia, Spain		
University of California-Davis, Sacramento, CA		
Pilot Study additional enrollments*		15
*(pilot + definitive)TOTAL	54	346

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FAQ Corner

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

Question: Can we give the study product (glutamine/maltodextrin) via the parenteral route?

Answer:
The study product **cannot** be given via the parenteral route. If the patient is receiving any enteral medication, please give the study product (via the enteral route) as well.

Question: Do we record tracheostomies as burn related operative procedures in REDCap?

Answer:
Do not record tracheostomies in REDCap on the Burn Related Operative Procedures form. Although the tracheostomy was likely due to an inhalation injury as a result of the burn injury, we are not collecting tracheostomies as burn related operative procedures for the purposes of the study.

Question: Do we record escharotomies as burn related operative procedures in REDCap?

Answer: Yes, please record escharotomies in REDCap on the Burn Related Operative Procedures form.

Question: Do we need to collect the percentage of adequacy received from oral nutrition?

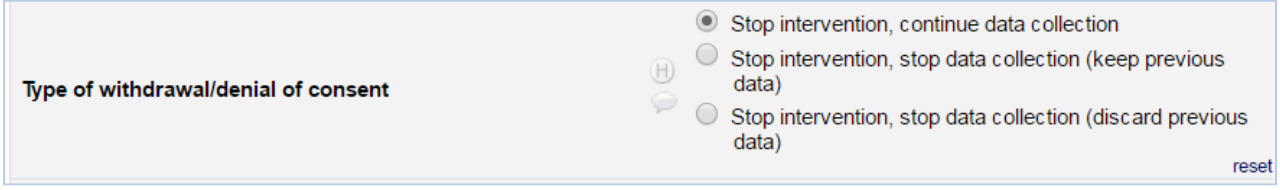
Answer:
No, we are no longer collecting percentage of adequacy received from oral nutrition. We have gone back to a simple 'Yes'/'No' response to the question 'Was Oral Nutrition given?'.

Question: Do we complete the 6 Month Survival Assessment, 6 months after ACU discharge?

Answer:
No, 6 Month Follow-up assessments are completed 6 months after ACU **admission**.
Example: Patient ID-R001 was admitted on 01-January-2017 and discharged on 01-March-2017, the 6 Month Follow-up assessments are completed on 01-July-2017 (+/- 2 weeks).

Question: Our patient is refusing to continue the investigational product (IP), what should we do ?

Answer:
Reassure the patient he or she has the right to stop participating in the study at any time. Next, explore why the patient does not want to continue taking the study IP. If the reason is related to the taste, ask if they are willing to try the IP mixed in a beverage or food they enjoy – let them tell you what they like. If the patient still wants to stop taking the IP, ask if you may continue to collect information about them related to their participation in the study. Let the patient know you will contact them to find out how they are doing 6 months after they were first admitted. If you are not able to obtain 6 month survival status, their participation was meaningless. Document the patient refusal to continue study intervention on the Hospital Overview Form (HOF), see screenshot below:



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IMPORTANT NOTES

Overall

- We would like to ask you to screen twice a day, once during the morning and a second time in the afternoon (before you leave for the day).

Things to keep in mind

- **Study Medication dosing on the 1st day of randomization – double doses or extra doses:**

  Please work to **ensure your patients receive as much of the prescribed daily dose as possible** on the first day of intervention **by administering double doses or additional doses**. You may need to request the pharmacy dispense additional doses on the day of randomization.

  Reminder: Do not given more than double the prescribed dose at one time.
  Give each dose at least one hour apart.

  Note: It is not a protocol violation if the patient receives less than 80% prescribed on the day of randomization.

- **You should be dissociating decisions** about tube feeds and administration of study intervention. If the patient is not tolerating tube feeds, we would encourage you to continue with the study medication. If the patient has been randomized to glutamine, it is a preferred fuel for starving enterocytes and the gut cells should like it.

CRS and REDCap

- When using the **password reset function** for the CRS or REDCap, if you do not receive the reset email within 15 minutes of submitting the request, please call the Project Lead or Project Assistant.

Studies pre-approved for co-enrollment:

- EpiFix or EpiBurn: Dehydrated Human Amnion Chorion Membrane (dHACM)
- Porcine Xenograft or Microbial cellulose in the treatment of partial thickness burns
- Antibiotic Concentration in Critical ill ICU patients in Sweden
- Propanolol
- Prospective Evaluation of the ReCell® Autologous Cell Harvesting Device For Specific Compassionate Use Cases
- Tetrodotoxin studies
- Vitamin D Supplementation in Burned Patients

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