THE RE-*ENERGIZE* STUDY

***A RandomizEd Trial of ENtERal Glutamine to minimIZE Thermal Injury***

# Dietitian Manual

Intended Audience: Dietitians

This study is registered at Clinicaltrials.gov.
Identification number NCT00985205

Critical Care Nutrition

CIHR IRSC
Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

Clinical Evaluation Research Unit

THE RE-*ENERGIZE* STUDY

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## Document History

| Version: Date | Superseded Version (Date) |
|---|---|
| Version 1: 10 December 2015 | Original version |
| Version 1.1: 29 January 2016 | 10 December 2015 |
| Version 1.2: 09 February 2016 | 29 January 2016 |
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## Study Contacts

| Name | Role | Contact Details |
|---|---|---|
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All questions related to study procedures should be directed to the Project Leader (PL).

In the event you are unable to reach the Project Leader, please contact the Project Assistant (PA). If you are unable to reach either the PL or PA, please contact the Principal Investigator (PI).

## Glossary

| | |
|---|---|
| ACU | Acute Care Unit (ICU or Burn Unit) |
| CERU | Clinical Evaluation Research Unit at Kingston General Hospital (Methods Centre) |
| CRF/eCRF | Case Report Form/electronic Case Report Form |
| CV | Curriculum Vitae |
| DAL | Delegation of Authority Log |
| EDCS | Electronic Data Capture System |
| EN | Enteral Nutrition |
| FDA | Food and Drug Administration (USA) |
| GCP | Good Clinical Practice |
| HC | Health Canada |
| hCG | Human Chorionic Gonadotropin (pregnancy indicator) |
| HOB | Head of Bed |
| IP | Investigational Product |
| PL | Project Leader or delegate |
| PN | Parenteral Nutrition |
| RC | Research Coordinator |
| REDCap™ | Research Electronic Data Capture system |
| SAE | Serious Adverse Event |
| SD | Study Day |
| SI | Site Investigator |
| Sub-I | Sub-Investigator |
| po | per os (by mouth) |

# Study Synopsis

Overview
The primary purpose of this study is to determine the overall treatment effect and safety of enteral glutamine administration to severely burn injured patients in acute care units (ACUs). We assert that glutamine administration will reduce acute care unit and hospital length of stay, decrease 6 month mortality, decrease hospital-acquired blood stream infections from Gram negative organisms, and improve the physical function of surviving burn injured patients.

**Study Design**
A large, multicenter, double-blind, pragmatic, randomized controlled trial of 1200 patients with severe burns randomly allocated to receive enteral glutamine or placebo.

**Setting**
Approximately 60 tertiary acute care burn centres in Canada, the United States, Europe, Latin America and Asia.

**Study Population**
1200 adult patients with deep 2$^{nd}$ and/or 3$^{rd}$ degree burns requiring skin grafting. For patients age 18 – 39 years we require a TBSA (Total Burn Surface Area) of ≥ 20%, or in the presence of an inhalation injury, a minimum of ≥ 15 % TBSA is acceptable. For patients age 40 – 59 years we require a TBSA of ≥ 15 %. For patients aged 60 years or older we require a TBSA of ≥ 10%.

**Study Intervention**
Patients will receive glutamine or maltodextrin (placebo/control) through their feeding tube every 4 hours, or orally 3 – 4 times a day, for a total of 0.5g/kg/day until 7 days after their last grafting operation, or discharge from the acute care unit, or 3 months after admission to the acute care unit, whatever comes first.

**Outcomes**

| | |
|---|---|
| Primary outcome: | Time to discharge alive |
| Secondary outcome: | 6-month mortality |
| Tertiary outcomes: | Health-related quality of life with particular focus on physical function<br>Incidence of acquired bacteremia due to Gram negative organisms<br>Hospital mortality<br>Duration of mechanical ventilation<br>Acute care unit length of stay<br>Hospital length of stay |

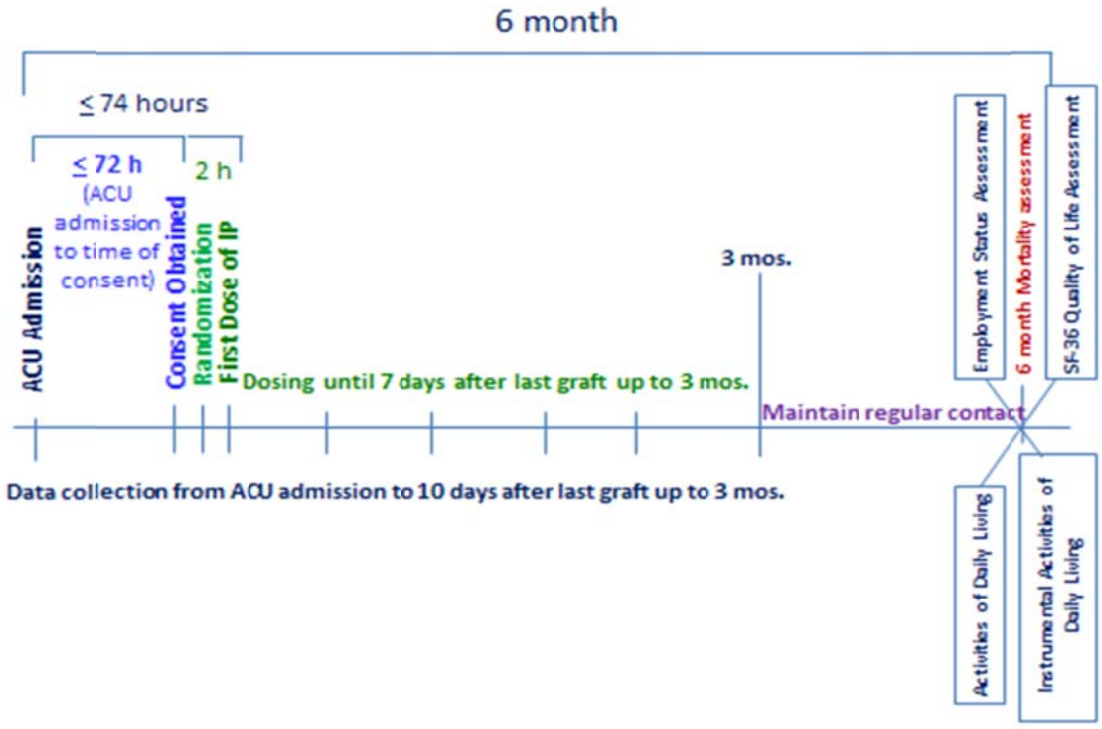
**Trial Duration**

*Study Recruitment Period*

4 years - based on approximately 1 patient per site per month, as demonstrated in the pilot study.

**Diagram of Study Overview**

Below is a diagrammatic representation of the RE-ENERGIZE Study. Refer to appropriate sections of the Study Procedures Manual for comprehensive instructions for study activities.



## Training

Each member of the site research team should be qualified by education, training and experience to assume responsibility for the proper conduct of the trial. The Site Investigator is responsible for ensuring that s/he and the local staff are adequately trained in GCP (GCP 4.1.1).

Each **Dietitian**, or study team member responsible for assessing and monitoring the nutritional needs of patients, must have documented training on the RE-ENERGIZE study. Study specific training will be provided by CERU Staff and conducted either in person or via webinar.

## Patient Population

**Inclusion Criteria**

1) **Deep 2nd and/or deep 3rd degree burns requiring grafting**
   The presence of deep 2nd degree and/or deep 3rd degree burns requiring grafting is an assessment that must be made by the surgeon/physician.

2) **Patient meets one of the following 3 criteria:**
   a. Patients 18 – 39 years of age with TBSA ≧ 20%
   b. Patients 18 – 39 years of age with TBSA ≧ 15% WITH inhalation injury
   c. Patients 40 – 59 years of age with TBSA ≥ 20%
   d. Patients ≥ 60 years of age with TBSA ≥ 10%

**Exclusion Criteria**

1) > 72 hours from admission to Acute Care Unit (ACU) to time of consent
   *This refers to admission to your ACU. If a patient is transferred from another facility, the clock starts from the time of admission to your unit. An exception would be a patient who has been an extended period of time at another facility post burn prior to admission to your unit.*

2) Patients younger than 18 years of age

3) In patients **without known renal disease**, renal dysfunction defined as a serum creatinine >171 mmol/L or a urine output of less than 500 ml/last 24 hours (or 80 ml/last 4 hours if a 24 hour period of observation is not available).

   In patients **with acute on chronic renal failure** (pre-dialysis), an absolute increase of >80 mmol/L from baseline or pre-admission creatinine or a urine output of <500 ml/last 24 hours (or 80 ml/last 4 hours) will be required.

   Patients with **chronic renal failure on dialysis** will be excluded.

4) Liver cirrhosis -Child's class C liver disease

5) Pregnancy (urine/blood tests for pregnancy will be done on all women of childbearing age by each site as part of standard of ACU practice)

6) Contra-indication for EN: intestinal occlusion or perforation, intra-abdominal injury. (Being NPO is not considered a contraindication for Enteral Nutrition).

7) Patients with injuries from high voltage electrical contact.

8) Patients who are moribund (not expected to survive the next 72 hours in the judgement of the Site Investigator or delegated doctor in charge).
*Note that an isolated DNR does not fulfil this criteria.*

9) Patients with extreme body sizes: BMI < 18 or > 50 kg/$m^2$
*Ideally BMI should be calculated using the patient's pre-burn dry weight. Given that there may be some subjectivity involved in the determination of BMI, err on the side of including the patient.*

*10)* Enrollment in another industry sponsored ICU intervention study *(co-enrollment in all non-randomized academic studies will be approved. For academic RCTs, forward a synopsis or abstract of the study to the project leader to obtain pre-approval of the study to which you would like to co-enroll.*

11) Received glutamine supplement for > 24 hours prior to randomization.
*This refers to consistent administration of glutamine over the 24 hr period prior to randomization. If the patient received random or intermittent doses of open label glutamine, discontinue the glutamine prior to randomization.*

12) Known allergy to maltodextrin, corn starch, corn, corn products or glutamine.

## Investigational Product

The active and control products will both be supplied in pre-packaged 5g packets. The active and control have the same visual appearance and taste.

**Nutrestore™ (L Glutamine)**
Nutrestore is an amino acid (L Glutamine) powder that is approved for oral use in short bowel syndrome by the FDA. L Glutamine is produced normally by the body and has important functions in regulation of gastrointestinal cell growth, function, and regeneration. Under normal conditions, glutamine concentration is maintained in the body by dietary intake and synthesis from endogenous glutamate. Data from clinical studies indicate that the role of and nutritional requirements for glutamine during burns, catabolic illness, trauma, and infection may differ significantly from the role of and nutritional requirements for glutamine in healthy individuals. Glutamine concentrations decrease and tissue glutamine metabolism increases during many catabolic disease states, and thus glutamine is often considered a "conditionally essential" amino acid.

**Maltrin® M100 Maltodextrin (control)**
The MALTRIN® M100 maltodextrin is produced by Grain Processing Corporation (GPC) and then packaged by Anderson Packaging for the trial. Maltodextrins are bland, low sweetness, pharmaceutical grade, white carbohydrate powders that are Generally Recognized As Safe (GRAS) as direct human food ingredients at levels consistent with current good manufacturing practices. They are prepared as a white powder by partial hydrolysis of corn starch with safe and suitable acids and/or enzymes. Patients will receive an iso-calorically delivered amount of maltodextrin (control) mixed with water or other liquids. Maltodextrin is a source of carbohydrate

commonly found in standard enteral nutrition and has no metabolic effects other than serving as a source of additional energy. The maltodextrin used in this study contains approximately 19 calories per 5g packet.

**Dosing**
Study intervention will be dosed in accordance with the patient's pre-burn dry weight and recorded in the eCRF. By dry weight, we mean prior to resuscitation and it is likely consistent with the usual weight recorded on a prior chart or obtained from a family member.

Patients will receive glutamine or maltodextrin through their feeding tube, every 4 hours enterally or TID to QID if po, for a total of 0.5g/kg/day.

a) Patients with a BMI <35 will receive 0.5g/kg/day of either glutamine or maltodextrin based on pre-burn dry weight (actual or estimated).
b) Patients with a BMI ≥35 will receive 0.5g/kg/day of either glutamine or placebo (maltodextrin) based on the adjusted body weight, as per the calculation below:

**Adjusted Body Weight (ABW) = Ideal Body Weight (IBW) based on a BMI of 25 + [(pre-burn dry weight – IBW) x 0.25]**

The patient's IP dosing weight should remain the same throughout the course of the study, with the following exception: IF the clinical team changes the weight used for drug dosing due to a clinically significant change in the patient's weight, the pharmacy will be notified and the study intervention dose adjusted in accordance with the patient's current drug dosing weight. Associated data will be recorded in the eCRF.

## Duration

**Patients will receive the study intervention from randomization until 7 days post last successful grafting operation, or until acute care unit discharge, or until 3 months after acute care unit admission, whatever comes first.**

*We recognize that defining the end of study treatment phase by 7 days post last successful graft may not be very exact or precise. There may be unique features to some patients that make it difficult to define. As guidance, we generally mean when the patient is over the acute phase of their illness and either discharged from the acute care unit or entering in their rehabilitation phase.*

## Standardization of Nutrition Practices

We recommend all study patients be fed in accordance with the Standardization of Nutrition Practices.

Given the metabolic complications and increased nutritional requirements in burns patients, the provision of nutrition support is a challenging task and variability in nutrition practices across burn units exists[1]. To reduce the effect of varying nutritional practices as confounding factors on

the outcomes of The RE-ENERGIZE study, it is important to standardize, *as much as possible*, the prescription of enteral and parenteral nutrition, micronutrient delivery and practices related to withholding feeds for high gastric residual volumes and use of motility agents in these patients.

Based on the literature and providing for some flexibility for current practices across the participating sites, we are recommending compliance with the following nutritional practices for all patients enrolled in the study. After reviewing the practices at all the participating sites, these ranges below will allow for most current practices to continue.

1) **Prescribed Energy needs are to be calculated using** Indirect Calorimetry, a predictive equation, or a simple weight-based formula. On average, this should lead to a prescription of 25 - 30 kcal/kg.

   Use pre-burn dry weight when calculating energy needs. For Obese patients, if your standard practice is to adjust for obesity, follow your standard practice. If you do not have an obesity adjustment practice, use the formula below.

   **Adjusted Body Weight (ABW) = Ideal Body Weight (IBW) based on a BMI of 25 + [(pre-burn dry weight – IBW) x 0.25]**

2) **Prescribed Protein needs are to be calculated using the following:**

   **According to % burn surface area**

   i. If > 50% burns, use 1.5 g/kg*/day to 2.5g/kg*/day
   ii. If < 50% burns, use 1.2 g/kg*/day to 2 g/kg*/day

   Pre-burn dry weight* should be used when calculating protein needs. For Obese patients, if your standard practice is to adjust for obesity, follow your standard practice. If you do not have an obesity adjustment practice, use the formula below.

   **Adjusted Body Weight (ABW) = Ideal Body Weight (IBW) based on a BMI of 25 + [(pre-burn dry weight – IBW) x 0.25]**

3) **Vitamin & Mineral Prescription should be given as follows or depending upon blood levels (if blood testing is done as part of routine practice) :**
   - Vitamin C: 0-1000 mg/day
   - Vitamin A: 0-10,000 IU/day
   - Vitamin D: according to serum levels
   - Vitamin E: 0-420 mg/day
   - Zinc (not elemental): 0-220 mg/day
   - Copper Sulfate: 0-4.5 mg/day
   - Selenium: 0-500 micrograms/day
   - Magnesium:0-600 mg/day
   - Folate: 0-1500 mg/day
   - Thiamin: 0-110 mg/day

***Early supplementation by high dose IV Vitamin C (66 mg/kg/hr) within the first 48 hrs is allowed [2]. Standard multivitamin/mineral preparations are allowed (IV, NG or po).***

*These ranges of vitamins/minerals/trace elements may be provided as supplementation over and beyond what is present in the standard enteral/parenteral nutrition.*

***OR***

*These ranges of vitamins/minerals/trace elements may be provided as the total amounts. This means that the amounts received from enteral/parenteral nutrition are to be subtracted from the total ranges and the remainder is given as supplements.*

**4) Specialized nutritional formulas are not allowed such as:**

i. Arginine enriched formulas (formulas that contain arginine > 6 g/L), eg:
- Pivot® (13 g/L)
- Perative (8 g/L)

ii. Glutamine supplements or formulas enriched with glutamine, eg:
- Impact® Glutamine (15 g/L)
- VIVONEX® Plus (13.5 g/L)
- GLUTASOLVE® (15 g/L)/other glutamine powders
- Juven® (7 g/L)

Formulas with glutamic acid inherently present are allowed

***To minimize any potential contamination, patients that have received glutamine for >24 hrs before randomization, should NOT be included.***

**5) Optimization of the Delivery of Enteral Nutrition:**
The use of enteral nutrition is preferred over parenteral nutrition in burn patients. Interruptions to the delivery of enteral nutrition should be minimized while adopting strategies to optimize the delivery of EN such as elevating the head of the bed to a minimum of 45 degrees (unless otherwise contraindicated), using a minimum gastric residual volume threshold of 250 ml (if you use a larger GRV threshold, that is acceptable), and the use of motility agents and small bowel feeding tubes as clinically indicated. Refer to Enteral Feeding Protocol in the Appendix A for more details.

Ongoing monitoring of the volumes of delivery of enteral nutrition and an action plan to ensure that the recommended prescribed needs are being met is recommended as part of the study protocol.

**6) Glycemic control:**
The use of a glycemic control protocol (or the use of insulin) to control blood sugars between the ranges of at least 80 mg/dL to a maximum of 180 mg/dL (4.4-10 mmol/L) is recommended in order to avoid hyperglycemia, while minimizing the risk of both iatrogenic hypoglycemia and other harms associated with a lower blood glucose target.

# Data Collection

Nutrition Data for the RE-ENERGIZE study is to be collected from ACU admission through Study day 12.

Worksheets for collecting data related to nutritional assessment and adequacy are provided for convenience. Please ensure the research coordinator has access to the information for entry into the EDCS, whether you are recording data on the worksheets or completing the data in the patient's chart.

**Nutrition Assessment/Timing (see Appendix B)**
Prescribed Energy and Protein Needs
On the Baseline Assessment form, record the date that the initial energy and protein needs were assessed after the patient was admitted to the ACU. If prescription information is not available, we will use the following:

- Calories = 25 kcal/kg/day
- Protein = 1.2 g/kg/day

Record the energy prescribed in kcals
Record the protein prescribed in grams

If the energy and protein prescription changes during the study period, record the date and the new prescription for calories and protein on the Nutrition Assessment/Timing form (example below).


IF THE PRESCRIPTION CHANGES FOR THIS PATIENT, ENTER THE DATE AND NEW PRESCRIPTION:
NOTE: ENERGY AND PROTEIN REQUIREMENTS ARE INDEPENDENT OF FORMULA PRESCRIBED.
DO NOT CHANGE PRESCRIPTION TO ACCOMMODATE FORMULA CHANGE.

| | |
|---|---|
| **Was another prescription made?** | ◉ Yes ○ No |
| **Assessment #2** | |
| **Date prescription made** | Today Y-M-D YYYY-MM-DD |
| Prescribed Energy Needs | XXXXX kcal |
| Prescribed Protein Needs | XXX g |

**Enteral and Parenteral Start Dates and Times**
Indicate if Enteral or Parenteral Nutrition was received during the first 12 days after ACU admission by selecting the appropriate response, see below:

| | |
|---|---|
| **Enteral Nutrition** | |
| **Was EN received during this ACU admission?** | ○ Yes, started during first 12 days of ACU admission ○ Yes, started after first 12 days of ACU admission ○ No |
| **Parenteral Nutrition** | |
| **Was PN received during this ACU admission?** | ○ Yes, started during first 12 days of ACU admission ○ Yes, started after first 12 days of ACU admission ○ No |

If EN or PN was started during the first 12 days after ACU admission, record the start date and time in the space provided, see below:

| | |
|---|---|
| **Was EN received during this ACU admission?** | ◉ Yes, started during first 12 days of ACU admission ○ Yes, started after first 12 days of ACU admission ○ No |
| **EN Start Date** | Today Y-M-D YYYY-MM-DD |
| **EN Start Time** | Now H:M HH:MM 24hr |

If EN or PN was received during this ACU stay, but it was not started until after the first 12 days of ACU admission, select “Yes, started after first 12 days of ACU admission”, see below:

| | |
|---|---|
| **Enteral Nutrition** | |
| **Was EN received during this ACU admission?** | ○ Yes, started during first 12 days of ACU admission<br>◉ Yes, started after first 12 days of ACU admission<br>○ No |
| **Parenteral Nutrition** | |
| **Was PN received during this ACU admission?** | ○ Yes, started during first 12 days of ACU admission<br>◉ Yes, started after first 12 days of ACU admission<br>○ No |

If EN or PN was not received during this ACU stay, select “No”.

**Enteral and Parenteral Stop Dates and Times**

If EN or PN was started within the first 12 days after ACU admission and permanently stopped during the first 12 days after ACU admission, indicate the actual stop date & time in the space provided, see below:

| | |
|---|---|
| **EN Stop Date & Time:** | ○ Same as death date & time<br>○ Still receiving EN after Day 12 post ACU admission<br>◉ Actual EN Stop date & time |
| EN Stop Date | Today Y-M-D<br>YYYY-MM-DD |
| EN Stop Time | Now H:M<br>HH:MM 24hr |

If the patient was still receiving EN or PN after 12 days post ACU admission, select the corresponding response, see below:

| | |
|---|---|
| **EN Stop Date & Time:** | ○ Same as death date & time<br>◉ Still receiving EN after Day 12 post ACU admission<br>○ Actual EN Stop date & time |

If the patient dies during the first 12 days after ACU admission and is still receiving EN or PN, select “Same as death date & time”.

.

Do <u>not</u> record temporary interruptions of EN and PN on the Nutrition Assessment / Timing form.

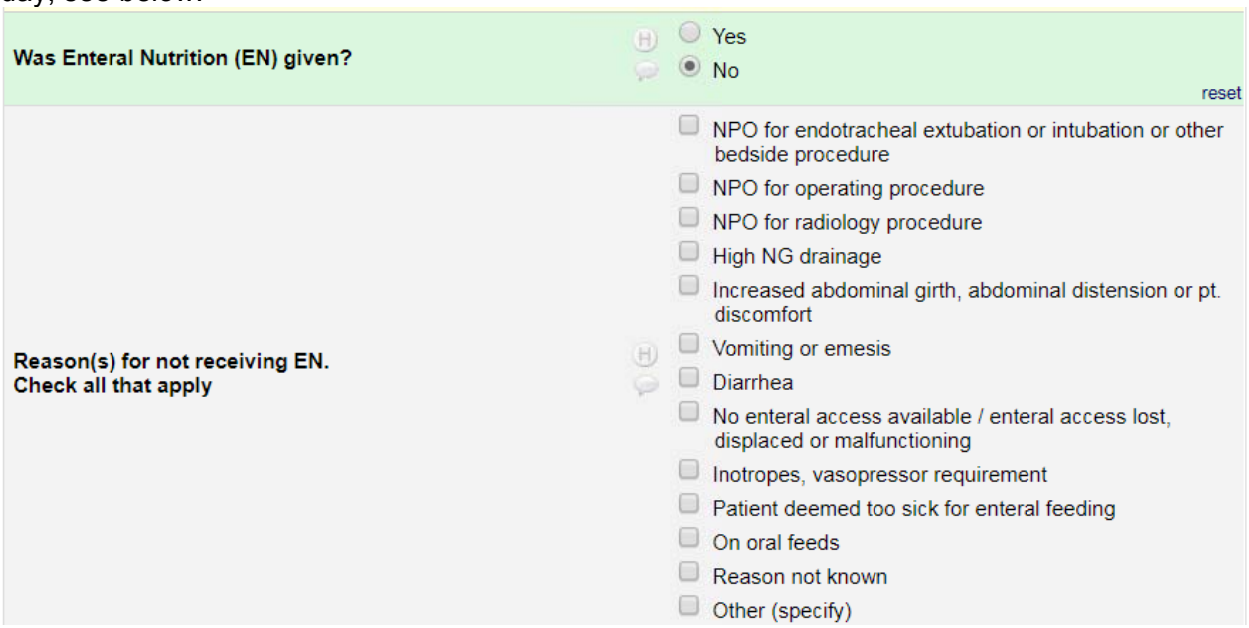
**Daily Nutrition Received (see Appendix C)**

This data is collected for the first 12 days of ACU admission.

<u>Enteral Nutrition</u> (EN)

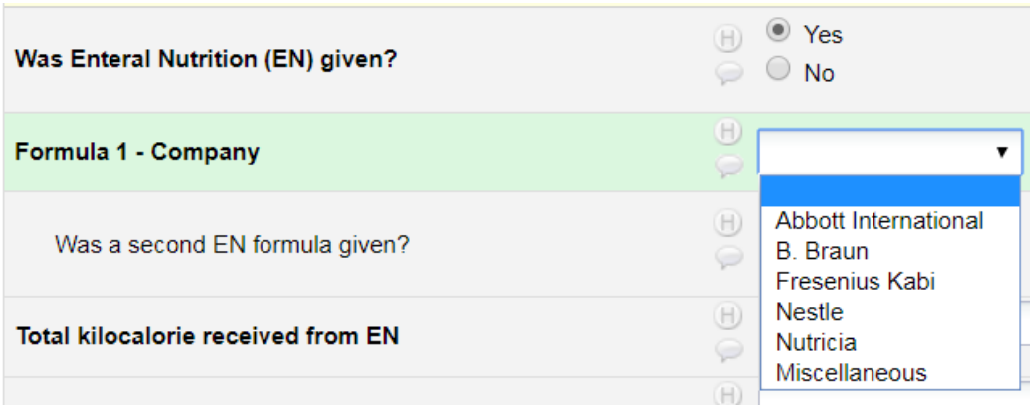
Record the date and enter the data on the corresponding study day.
Indicate whether or not the patient received EN that day by selecting “Yes” or “No”.

If EN was **not** received, indicate all the reasons the patient did not receive EN on the specified day, see below:

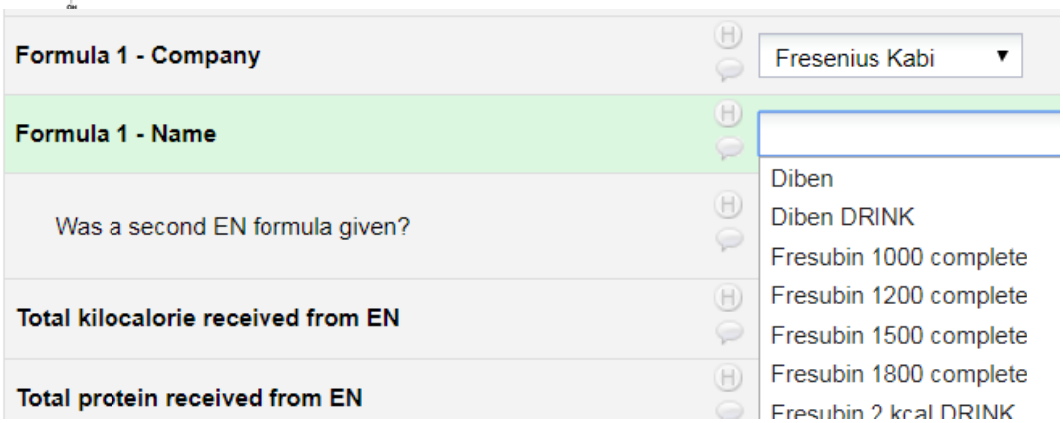



If EN was received, indicate the formula(s) (up to 3 different formulas) that provided the most nutrition on that study day:

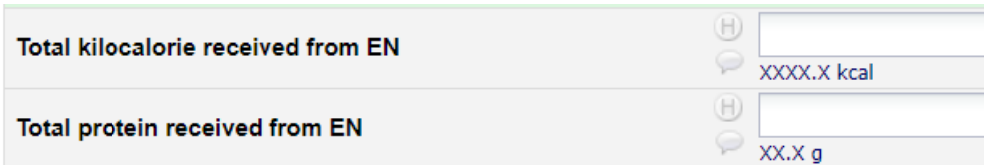
- Select or enter the name of the company for the formula that provided the most nutrition on that study day, see below:




- Select or enter the name of the formula that provide the most nutrition on that study day, see example below:



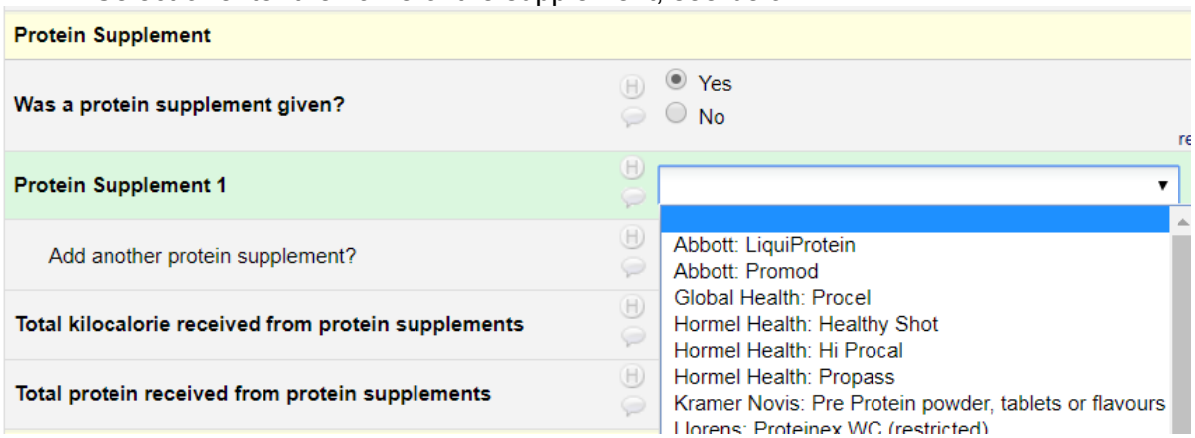

- If more than one formula was given on that study day, select “Yes” to the question “Was a second EN formula given?” and repeat the steps above.
- Enter the total kcals received from all EN formulas on that study day
- Enter the total grams of protein received from all EN formulas on that study day



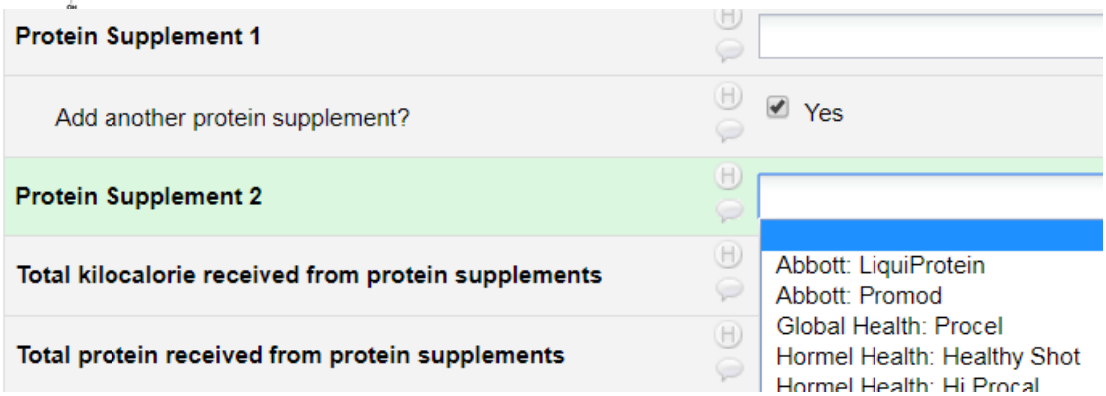

<u>Protein Supplements</u>

Indicate whether or not the patient received a protein supplement that day by selecting “Yes” or “No” in the PROTEIN SUPPLEMENT row. If a protein supplement was received:

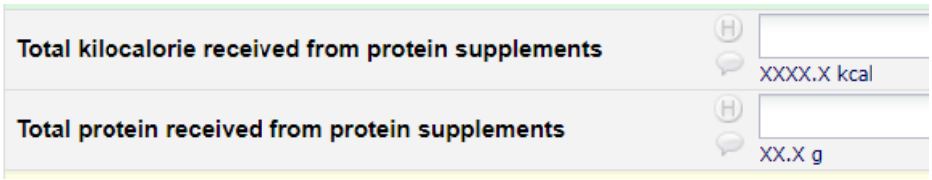
- Select or enter the name of the supplement, see below:




If a second Protein Supplement has given, select “Yes” to “Add another protein supplement?” and select or enter the name of the second protein supplement, see below:



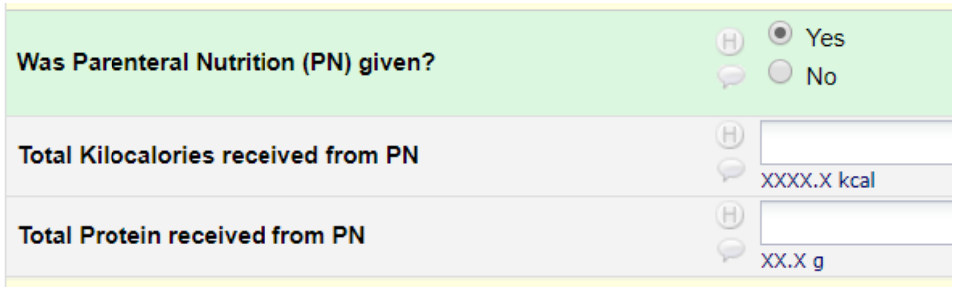

- Enter the total kcals received from the protein supplement(s)
- Enter the total grams of protein received from the protein supplement(s)




You may enter up to 2 protein supplements daily. If more than 2 protein supplements were given, enter the 2 that provided the most energy and protein on that study day.

Parenteral Nutrition (PN)
Indicate whether or not the patient received PN that day by selecting “Yes” or “No”.

If PN was received:
- Enter the total kcals received from PN
- Enter the total grams of protein received from PN

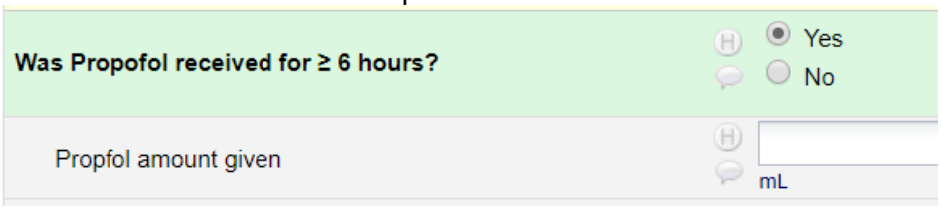



Oral Nutrition
Indicate whether or not the patient received oral nutrition that day by selecting “Yes” or “No”.

Propofol
Indicate whether or not the patient received a continuous infusion of Propofol for ≥ 6 hours that day by selecting “Yes” or “No”.

If a continuous infusion of Propofol for ≥ 6 hours was received:

- Enter the volume of Propofol received in mL.




Insulin

Indicate whether or not the patient received insulin on that study day by selecting “Yes” or “No”.

If insulin was received:

- Enter the amount the total insulin received that study day in units.

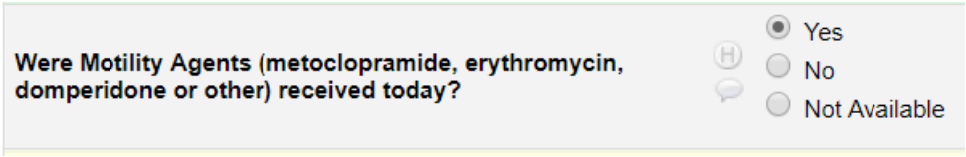

Opiates

Indicate whether or not the patient received opiates that study day by selecting “Yes” or “No”.


Motility Agents

Indicate whether or not the patient received motility agents that day by selecting “Yes” or “No”.

Please do not include stool softeners or bulk fibre such as dulcolax, senokot, or metamucil.



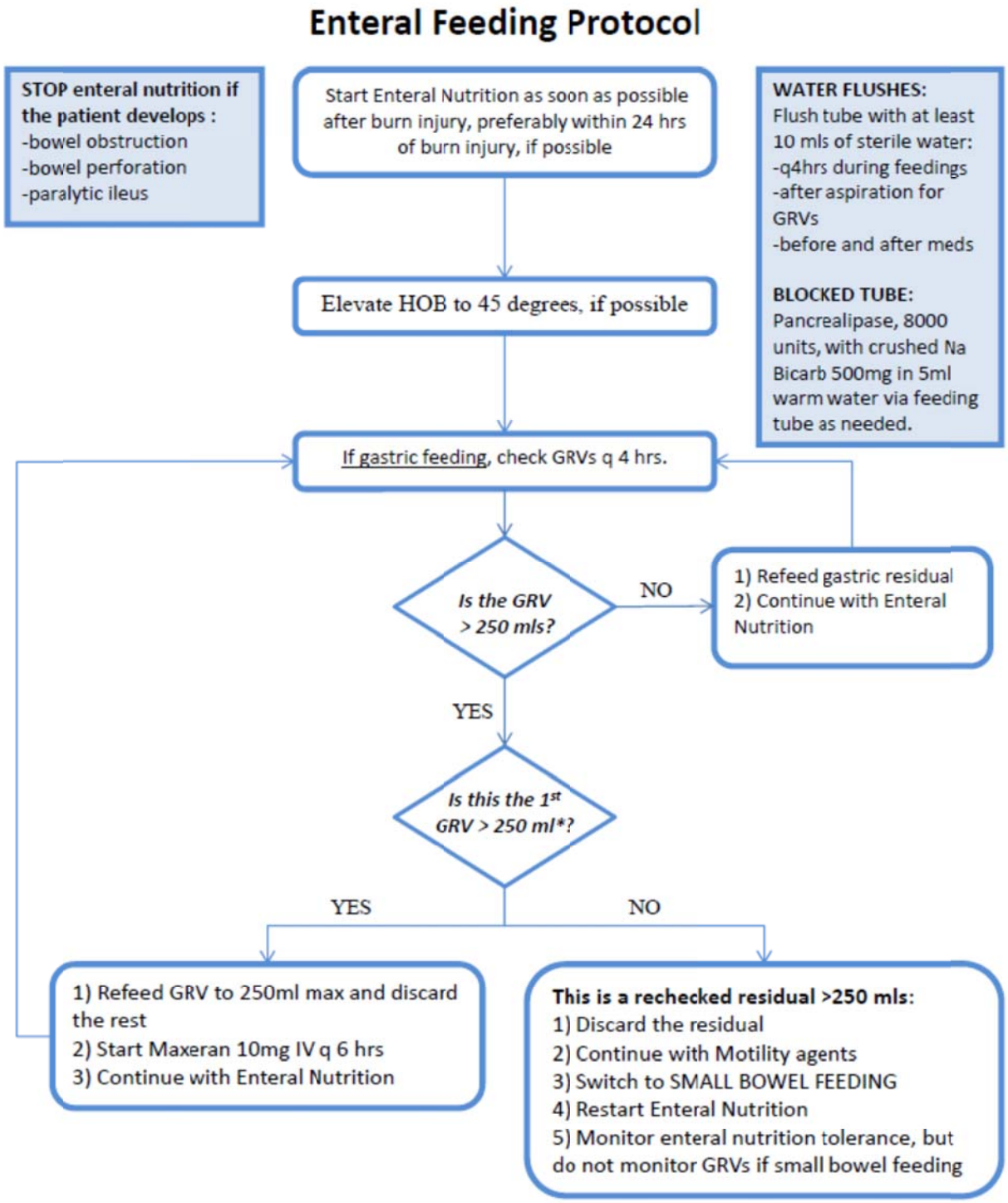
# Appendices

Appendix A:  Enteral Feeding Protocol

Appendix B:  Nutritional Assessment/Timing form

Appendix C:  Daily Nutrition form

## Appendix A: Enteral Feeding Protocol




* Gastric residual volume (GRV) of 250 mls is the minimum threshold volume. Volumes higher than 250 mls are acceptable if allowed at the individual site.

## Appendix B: Nutrition Assessment/Timing Form





Patient ID _____

### Nutrition Assessment

| | | |
|---|---|---|
| **Baseline Assessment** | | |
| Date prescription made (YYYY-MM-DD) | | |
| Prescribed Energy Needs (kcal) | | |
| Prescribed Protein Needs (grams) | | |
| Was another prescription made? | ☐ Yes ☐ No | |
| **Assessment #2** | | |
| Date prescription made (YYYY-MM-DD) | | |
| Prescribed Energy Needs (kcal) | | |
| Prescribed Protein Needs (grams) | | |
| Was another prescription made? | ☐ Yes ☐ No | |
| **Assessment #3** | | |
| Date prescription made (YYYY-MM-DD) | | |
| Prescribed Energy Needs (kcal) | | |
| Prescribed Protein Needs (grams) | | |
| Was another prescription made? | ☐ Yes ☐ No | |
| **Enteral Nutrition** | | |
| Was Enteral Nutrition (EN) received during this ACU admission? | ☐ Yes, started during first 12 days of ACU admission<br>☐ Yes, started after first 12 days of ACU admission<br>☐ No | |
| If "YES", record EN Start date and time: | (YYYY-MM-DD) | (HH:MM, 24hr) |
| EN Stop date and time: | ❑ Same as death date & time<br>❑ Still receiving EN 12 days post ACU admission<br>❑ Actual EN stop date & time (enter below) | |
| | (YYYY-MM-DD) | (HH:MM, 24hr) |
| **Parenteral Nutrition** | | |
| Was Parenteral Nutrition (PN) received during this ACU admission? | ☐ Yes, started during first 12 days of ACU admission<br>☐ Yes, started after first 12 days of ACU admission<br>☐ No | |
| If Yes, record PN Start date and time: | (YYYY-MM-DD) | (HH:MM, 24hr) |
| PN Stop date and time: | ❑ Same as death date & time<br>❑ Still receiving PN 12 days post ACU admission<br>❑ Actual PN stop date & time (enter below) | |
| | (YYYY-MM-DD) | (HH:MM, 24hr) |

**Appendix C: Daily Nutrition Form**

THE RE-ENERGIZE STUDY

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## Daily Nutrition (1/2)

Patient ID

*(Collect from Study Day 1 through Study Day 12 only)*

Page #:_____

| Date (YYYY-MM-DD) | | | | |
|---|---|---|---|---|
| Enteral Nutrition (EN) given? | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No | ☐ Yes ☐ No |
| **If NO, EN not received (Select ALL reasons that apply)** | | | | |
| NPO for endotracheal extubation or intubation or other bedside procedure | ☐ | ☐ | ☐ | ☐ |
| NPO for operating procedure | ☐ | ☐ | ☐ | ☐ |
| NPO for radiology procedure | ☐ | ☐ | ☐ | ☐ |
| High NG drainage | ☐ | ☐ | ☐ | ☐ |
| Increased abdominal girth, abdominal distension or pt. discomfort | ☐ | ☐ | ☐ | ☐ |
| Vomiting or emesis | ☐ | ☐ | ☐ | ☐ |
| Diarrhea | ☐ | ☐ | ☐ | ☐ |
| No enteral access available / enteral access lost, displaced or malfunctioning | ☐ | ☐ | ☐ | ☐ |
| Inotropes, vasopressor requirement | ☐ | ☐ | ☐ | ☐ |
| Patient deemed too sick for enteral feeding | ☐ | ☐ | ☐ | ☐ |
| On oral feeds | ☐ | ☐ | ☐ | ☐ |
| Reason not known | ☐ | ☐ | ☐ | ☐ |
| Other (specify) | | | | |
| **If YES, EN received (Complete below)** | *Do NOT use formulas with (restricted) beside the name in REDCap™* | | | |
| Formula 1 (company and formula name) | | | | |
| Formula 2 (company and formula name) | | | | |
| Formula 3 (company and formula name) | | | | |
| Total Kilocalories from EN (kcal) | | | | |
| Total Protein from EN (g) | | | | |

THE RE-ENERGIZE STUDY



# Daily Nutrition (2/2)

Patient ID _____

*(Collect from Study Day 1 through Study Day 12 only)*

Page #:_____

| Date (YYYY-MM-DD) | | | | |
|---|---|---|---|---|
| **Was a Protein Supplement given?** | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No |
| Protein Supplement Name(s) | | | | |
| Total Calories (kcal) from Protein Supplement | | | | |
| Total Protein (g) from Protein Supplement | | | | |
| **Was Parenteral Nutrition (PN) given?** | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No |
| Total Calories (kcal) from PN | | | | |
| Total Protein (g) from PN | | | | |
| **Oral Nutrition given?** | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No |
| **Medications** | | | | |
| **Was Propofol received for ≥ 6 hours?** | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No |
| Volume of propofol received (mL) | | | | |
| **Was Insulin received?** | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available |
| Insulin total dose (units) | | | | |
| **Were Opiates received?** | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available |
| **Were Motility Agents received?** (metoclopramide. erythromycin, domperidone, other) | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available | ☐ Yes<br>☐ No<br>☐ Not Available |

## References

[1] Masters B, Wood F. Nutrition support in burns--is there consistency in practice? J Burn Care Res. 2008 Jul-Aug;29(4):561-71.

[2] Tanaka H, Matsuda T, Miyagantani Y, et al.Reduction of Resuscitation Fluid Volumes in Severely Burned
Patients Using Ascorbic Acid Administration. A Randomized, Prospective Study. Arch Surg. 2000;135:326-331