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The RE-ENERGIZE study: a RandomisEd trial of ENtERal Glutamine to minimIZE thermal injury

Submission date	Recruitment status	[X] Prospectively registered
13/01/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/01/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/03/2019	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT00985205

Secondary identifying numbers
CIHR #190808, MCT-94834; DOD# 09155001

Study information

Scientific Title
Effects of enteral glutamine supplementation on mortality and infectious morbidity in severely burned patients: a multicentre randomised double blind controlled trial

Acronym
RE-ENERGIZE

Study objectives
This research proposal is based on the following hypotheses:
1. Enteral glutamine administration decreases in-hospital mortality in adult subjects with severe thermal burn injuries
2. Enteral glutamine administration decreases infectious morbidity and shortens length of care in adult subjects with severe thermal burn injuries
3. Enteral glutamine administration decreases the cost of care of adult subjects with severe thermal burn injuries

As of 21/03/2012, the following changes have been made to the record.
Anticipated start date has been modified from 01/06/2010 to 01/12/2010.
Anticipated end date has been modified from 01/06/2012 to 01/03/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added on 21/03/2012:
Ethics approval expires on 7th February 2013.

Added 25/05/2010:
Colorado Multiple Institutional Review Board approved on the 7th April 2010 (ref: 10-0046).
Expires 6th April 2011.

Study design
Multicentre randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Severe thermal burn injuries

Interventions
Patients will be randomly allocated to two groups:

Glutamine group:
Patients will receive glutamine (L-glutamine) powder mixed with water through their feeding tube, every 4 hours or three times a day if given orally, for a total of 0.5 g/kg/day. The glutamine powder will be supplied in pre-packaged aliquots of 5 grams and will be delivered to the ICU in blinded sachets and will be mixed in with water at the bedside by the patient's nurse.

Control group:
Patients will receive maltodextrin (placebo) mixed with water instead of glutamine.

Joint sponsor details:
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University of Colorado (USA)
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Death: Hospital mortality recorded until complete healing, defined as 7 days after the last grafting procedure.

Secondary outcome measures
1. Six-month mortality: mortality recorded during the 6 months following admission
2. Incidence of infections: according to the Centers for Disease Control and Prevention (CDC) or similar definitions for ventilation-related pneumonia, central line infection, positive blood culture, including germ identification, wound infection. Others: unusual infection such as abscesses, meningitis, peritonitis, etc.
3. Length of care (defined as length of healing): defined as 7 days after the last grafting operation

4. Length of mechanical ventilation: number of days on ventilator
5. Clinical status in the ICU: APACHE score at entry and SOFA score every day during the ICU stay until the discontinuation of mechanical ventilation. These scores are derived from the clinical and biological monitoring of the patients in the ICU and are standardised. All data needed for the calculation of these scores will be transferred to our electronic database and calculated automatically.
6. Length of time in the ICU. This will include all days with assisted ventilation. When a patient will be re-admitted to the ICU within 48 hrs for assisted ventilation after having been discharged, the total ventilation/day will be taken into account.

Overall study start date
01/06/2010

Completion date
01/06/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/03/2012
1. Total Burn Surface Area (TBSA):
TBSA ≥ 20% for patients ages 18 - 59 years OR
TBSA ≥ 10% for patients ages 60 - 80 years
2. Deep 2nd and/or 3rd degree burns requiring grafting
3. Age + TBSA = 40-119

Previous inclusion criteria
1. Age + total burn surface area (TBSA) = 60 - 120 (upper limit not included)
2. Deep 2nd and/or 3rd degree burns
3. TBSA greater than or equal to 20%

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
Current exclusion criteria as of 21/03/2012
1. > 72 hrs from admission to ICU to time of consent
2. Patients > 80 yrs or < 18 yrs of age

3. Liver cirrhosis - Child s class C liver disease
4. Pregnancy
5. Absolute contra-indication for EN (intestinal occlusion or perforation, abdominal injury)
6. Patients admitted > 48 hrs post burn (for patients that receive standardized burn care and resuscitation
prior to admission to ICU, this exclusion criteria may be extended to Patients admitted > 96 hrs post
burn; if this is the case consent must be obtained within 24 hrs of admission to burn ICU according to
the judgement of the Site Investigator)
7. Patients with injuries from high voltage electrical shock
8. Patients who are moribund
9. Patients with BMI < 18 or > 50
10. Enrollment in another industry sponsored ICU intervention study (co-enrollment in academic studies will
be considered on a case by case basis)
11. Received glutamine supplement for > 24 hrs prior to randomization
12. Known allergy to maltodextrin, corn starch, corn, or corn products

Previous exclusion criteria
1. Greater than 48 hours from admission to intensive care unit (ICU) to time of consent
2. Patients older than 80 years or younger than 18 years of age (age of maturity for an eligible patient to obtain consent is 18 years in Canada and in the United States of America)
3. Liver cirrhosis: Child's class C liver disease
4. Pregnancy (urine/blood tests for pregnancy will be done on all women of childbearing age by each site as part of standard of ICU practice)
5. Associated multiple fractures or severe head trauma
6. Absolute contra-indication for enteral nutrition (EN): intestinal occlusion or perforation, abdominal injury
7. Patients admitted more than 48 hours post-burn (for patients that receive standardised burn care and resuscitation prior to admission to ICU, this exclusion criteria may be extended to "Patients admitted more than more than 72 hours post-burn" according to the judgement of the Site Investigator)
8. Patients with injuries from high voltage electrical shock
9. Patients who are moribund
10. Patients with extreme body sizes: body mass index (BMI) less than 18 or greater than 50 kg /m^2
11. Enrolment in another industry sponsored ICU intervention study (co-enrolment in academic studies will be considered on a case by case basis)

Date of first enrolment
01/06/2010

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
University of Colorado Denver
Aurora
United States of America
80045

Sponsor information

Organisation
Clinical Evaluation Research Unit (CERU) (Canada)

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Sponsor type
Research organisation

Website
http://www.kgh.on.ca/

ROR
https://ror.org/02nkfan21

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research - http://www.cihr-irsc.gc.ca (ref: 190808, MCT-94834)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
U.S. Department of Defense (ref: 09155001)

Alternative Name(s)
United States Department of Defense, Department of Defense, U.S. Dept of Defense, US Department of Defense, DOD, USDOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/12/2017	13/03/2019	Yes	No