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REducing Deaths due to OXidative Stress: the REDOXS© Study

Submission date	Recruitment status	[X] Prospectively registered
27/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/03/2016	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.criticalcarenutrition.com/redoxs

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00133978

Secondary identifying numbers
MCT-82214

Study information

Scientific Title
REducing Deaths due to OXidative Stress: a randomised trial of glutamine and anti-oxidant supplementation in critically ill patients

Acronym
REDOXS©

Study objectives
Primary hypothesis:
Glutamine and antioxidant supplementation improves the survival of critically ill patients or reduces 28 day mortality.

Secondary hypothesis:
Glutamine and antioxidant supplementation will have a favourable effect on duration of mechanical ventilation, stay in Intensive Care Unit (ICU) and hospital, development of infectious complications, multiple organ dysfunction, antibiotic use, mitochondrial function and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of Queen's University Health Sciences and Affilated Teaching Hospitals (Canada), 22/03/2006

Study design

Multicentre non-pharmaceutical randomised factorial 2x2 design, placebo trial with study participants, investigator, caregiver, study nurses gathering data, outcome assessor, and data analyst blinded.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at http://www.criticalcarenutrition.com/index.php?option=com_content&task=view&id=19&Itemid=42

Health condition(s) or problem(s) studied
Severe organ dysfunction/critical illness

Interventions
1. Glutamine: 0.35 g/kg/day glutamine parenterally and 30 g/day enterally for a maximum of 28 days
2. Antioxidants: 500 µg of selenium/day parenterally and selenium 300 µg, zinc 20 mg, beta carotene 10 mg, vitamin E 500 mg, and vitamin C 1500 mg per day enterally for a maximum of 28 days
3. Glutamine and Antioxidants: Combination of glutamine and antioxidant treatments once daily for a maximum of 28 days
4. Placebo: normal saline parenterally and matching enteral placebo for a maximum of 28 days

Intervention Type
Supplement

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Glutamine and antioxidant supplementation

Primary outcome measure
Mortality at 28th day

Secondary outcome measures
1. Duration of mechanical ventilation, end of ICU stay
2. Stay in ICU and hospital, end of ICU and hospital stay
3. Development of infectious complications, throughout ICU stay
4. Multiple organ dysfunction, throughout ICU stay
5. Antibiotic use, throughout ICU stay

6. Mitochondrial function, throughout ICU stay
7. 36-item Short Form health survey (SF-36), quality of life survey, at three months and six months from ICU admission

Overall study start date
01/01/2007

Completion date
31/01/2010

Eligibility

Key inclusion criteria
1. Mechanically ventilated adult patients (more than or equal to 18 years old, either sex) admitted to ICU
2. Two or more of the following organ failures related to their acute illness:
2.1. A Partial Pressure of Oxygen in Arterial Blood (PaO2)/Fraction of Inspired Oxygen (FiO2) ratio of less than or equal to 300
2.2. Clinical evidence of hypoperfusion defined as the need for vasopressor agents (norepinephrine, epinephrine, vasopressin, more than or equal to 5 µg/kg/min of dopamine, or more than or equal to 50 µg/min phenylephrine) for greater than or equal to two hours
2.3. In patients without known renal disease, renal dysfunction defined as a serum creatinine more than or equal to 171 µmol/L or a urine output of less than 500 ml/last 24 hours (or 80 ml /last four hours if a 24 hour period of observation not available). In patients with acute on chronic renal failure (pre-dialysis), an absolute increase of more than or equal to 80 µmol/L from baseline or pre-admission creatinine or a urine output of less than 500 ml/last 24 hours (or 80 ml /last four hours) will be required
2.4. A platelet count of less than 50 x 10^9/L

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1200

Key exclusion criteria
1. More than 24 hours from admission to ICU
2. Patients who are moribund (not expected to be in ICU for more than 48 hours due to imminent death)
3. A lack of commitment to full aggressive care (anticipated withholding or withdrawing treatments in the first week)

4. Absolute contraindication to enteral nutrients (e.g., Gastro-Intestinal (GI) perforation, obstruction or no GI tract access for any reason)
5. Patients with severe acquired brain injury:
5.1. Significant head trauma (defined as an injury, in the opinion of the investigator, that represents a severe, disabling, or fatal brain injury)
5.2. Grade four or five subarachnoid haemorrhage
5.3. Stroke resulting in coma and intubation
5.4. Post-cardiac arrest with suspected significant anoxic brain injury
6. Seizure disorder requiring anticonvulsant medication
7. Cirrhosis - Child's class C liver disease
8. Metastatic cancer or Stage IV Lymphoma with life expectancy less than six months
9. Routine elective cardiac surgery (patients with complicated peri-operative course requiring pressors, Intra-Aortic Balloon Pump (IABP), ventricular assist devices can be included)
10. Patients with primary admission diagnosis of burns (more than or equal to 30% Body Surface Area [BSA])
11. Weight less than 50 kg or greater than 200 kg
12. Pregnant patients or lactating with the intent to breastfeed
13. Previous randomisation in this study
14. Enrolment in a related ICU interventional study

Date of first enrolment
01/01/2007

Date of final enrolment
31/01/2010

Locations

Countries of recruitment
Canada

Study participating centre
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Sponsor type
University/education

Website
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ROR
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Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (ref: MCT-82214)

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
Fresenius-Kabi (Germany)

Funder Name
Clinical Teachers Association of Queens University (Canada)

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?
Basic results				No	No
Other publications	rationale and study design	01/08/2006		Yes	No
Results article	results	18/04/2013		Yes	No