

REducing Deaths due to OXidative Stress: the REDOXS© Study

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

Plain English summary of protocol
Not provided at time of registration

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00133978

Protocol serial number
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 Affiliated 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

Study type(s)

Treatment

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(s)

Mortality at 28th day

Key secondary outcome(s)

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

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 $\mu\text{mol/L}$ 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 $\mu\text{mol/L}$ 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 $50 \times 10^9/\text{L}$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Kingston General Hospital

Kingston

Canada

K7L 2V7

Sponsor information

Organisation

Queen's University (Canada)

ROR

<https://ror.org/02y72wh86>

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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/04/2013		Yes	No
Basic results				No	No
Other publications	rationale and study design	01/08/2006		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes