# REducing Deaths due to OXidative Stress: the REDOXS© Study

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
27/12/2006		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
27/12/2006		[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

# Contact information

# Type(s)

Scientific

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Public

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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 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

# 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:  $500 \mu g$  of selenium/day parenterally and selenium  $300 \mu g$ , zinc 20 m g, beta carotene 10 m g, vitamin E 500 m g, and vitamin C 1500 m g 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  $\mu$ g/kg/min of dopamine, or more than or equal to 50  $\mu$ g/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  $50 \times 10^9/L$ 

# 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, Canadian Institutes of Health Research (CIHR), CIHR\_IRSC, 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