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The effects of blood glucose management on 90-day all-cause mortality intensive care unit (ICU) patients

Submission date
26/08/2004

Recruitment status
No longer recruiting

Registration date
25/10/2004

Overall study status
Completed

Last Edited
18/08/2010

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Simon Finfer

Contact details
Intensive Care Unit
Royal North Shore Hospital
Pacific Highway
St. Leonard's
Sydney
Australia
2065
+61 (0)2 9926 8656
sfinfer@med.usyd.edu.au

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00175331

ClinicalTrials.gov (NCT)
NCT00220987

Protocol serial number
293201; SUGAR ; NICE

Study information

Scientific Title
A multi-centre, open label randomised stratified controlled trial of the effects of blood glucose management on 90-day all-cause mortality in a heterogeneous population of intensive care unit (ICU) patients

Acronym
NICE-SUGAR STUDY

Study objectives
The hypothesis is that there is no difference in the relative risk of death between patients assigned a glucose range of 4.5 - 6.0 mmol/l and those assigned a glucose range of less than 10.0 mmol/l with insulin being infused if blood glucose exceeds 10.0 mmol/l, and adjusted when needed to maintain blood glucose of 8.0 - 10.0 mmol/l.

Acronym meaning: Normoglycaemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Canadian main site: Clinical Research Ethics Board of the University of British Columbia, Vancouver approved on 21st March 2006

Primary study design
Interventional

Study design
Randomised, parallel, two armed trial, with outcome assessor and data analyst blinding

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hyperglycaemia in critically ill patients

Interventions
The total projected recruitment for this trial is 6000 patients: 4000 in Australia and New Zealand (between April 2005 and December 2006) and 2000 in Canada (between May 2006 and September 2009). The Canadian leg of the trial will start on 01/05/2006 and is anticipated to run until the 30/09/2009.

Interventions for all participating centres:
Each participant will be randomised to receive an insulin sliding scale regimen to control blood glucose concentration between 4.5 - 6.0 mmol/l or insulin infused if blood glucose exceeds 10.0 mmol/l, and adjusted when needed to maintain blood glucose between 8.0 - 10.0 mmol/l

The trial sponsors for the Canadian leg of trial are:
1. The University of British Columbia
2329 West Mall
Vancouver
BC Canada
V6T 1Z4
2. Vancouver Coastal Health Research Institute
828 West 10th Avenue
Vancouver
BC, Canada
V5Z 1L8
3. George Institute for International Health

For further information on Canadian arm of trial, please contact the following:
1. Dr Vinay Dhingra at vinay.dhingra@vch.ca
2. Denise Foster, RN, CRC at Denise.Foster@vch.ca

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Glucose, insulin

Primary outcome(s)
90 day all-cause mortality

Key secondary outcome(s)
Determined over the same period (90 days):
1. Death in intensive care unit by day 28 and by 90 days
2. Length of intensive care unit stay
3. Length of hospital stay
4. The need for organ support (intropes, renal replacement therapy and positive pressure ventilation)
5. Incidence of blood stream infections
6. Incidence and severity of hypoglycaemia

Also in a subgroup of patients admitted with a diagnosis of traumatic brain injury, a follow up to determine long term functional status as determined by Extended Glasgow Outcome Scores (GOSE) will be collected at day 90 and six months.

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Patients (18 years or over, either sex) that are expected to require treatment in the ICU that extends beyond the calendar day following the day of admission
2. Patient has an arterial line in place or placement of an arterial line is imminent (within the next hour) as part of routine ICU management

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Patients are excluded from the study if ONE or MORE of the following criteria are present:
1. Age less than 18 years
2. Imminent death and the treating clinicians are not committed to full supportive care
3. Patients admitted to the ICU for treatment of diabetic ketoacidosis or hyperosmolar state
4. Patients that are expected to be eating before the end of the day following admission
5. Patients who have suffered hypoglycaemia without documented full neurological recovery
6. Patients thought to be at abnormally high risk of suffering hypoglycaemia
7. If a patient has previously been enrolled in the study
8. If the patient cannot provide prior informed consent, there is documented evidence that the patient has no legal surrogate decision maker and it appears unlikely that the patient will regain consciousness or sufficient ability to provide delayed informed consent
9. The patient has been in the study ICU or another ICU for longer than 24 hours for this admission

Date of first enrolment
04/04/2005

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
Australia

Canada

New Zealand

Study participating centre
Intensive Care Unit
Sydney
Australia
2065

Sponsor information

Organisation
Australian and New Zealand Intensive Care Society (Australia)

ROR
https://ror.org/007847151

Funder(s)

Funder type
Research council

Funder Name
Australian National Health and Medical Research Council (NHMRC) (Australia) (ref: 293201)

Funder Name
New Zealand Health Research Council (New Zealand) (ref: 05/078)

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - www.cihr-irsc.gc.ca (ref: MCT-80244)

Results and Publications

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?
Results article	results	26/03/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes