

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	<input checked="" type="checkbox"/> Prospectively registered
Registration date 25/10/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/08/2010	Condition category Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.thegeorgeinstitute.org>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00220987

Secondary identifying numbers

293201; SUGAR NCT00175331; NICE NCT00220987

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

Study design

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

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

90 day all-cause mortality

Secondary outcome measures

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.

Overall study start date

04/04/2005

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

6000 (2207 patients recruited as of 4/08/06)

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)

Sponsor details

Level 3, 10 Levers Terrace

Carlton

Victoria

Australia

3053

Sponsor type

Research organisation

Website

<http://www.anzics.com.au/ctg/about.htm>

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

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?
Results article	results	26/03/2009		Yes	No