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Pilot effectiveness of randomised mandatory insulin therapy

Submission date	Recruitment status	[_] Prospectively registered
23/05/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/07/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
12/03/2018	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Pilot Effectiveness of Randomised Mandatory Insulin Therapy (PERMIT)

Acronym
PERMIT

Study objectives
Current information as of 23/07/2009:
In patients requiring more than 48 hours of critical care treatment, mandatory insulin therapy, in comparison to usual sliding scale insulin therapy will not alter glycaemic control (including the number of severe hypoglycaemic events), but will modulate the derangements in the somatotrophic axis seen in critically ill patients.

Initial information at time of registration:
In patients requiring 5 or more days of critical care treatment, giving mandatory insulin therapy, compared to usual sliding scale insulin therapy as required, the number of severe hypoglycaemic events will be unchanged.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Research Ethics Committee (REC) C, ref: 05/Q1606/103

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Intensive care admission

Interventions
Sliding scale insulin versus mandated insulin

Intervention Type

Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Insulin

Primary outcome measure
Current information as of 23/07/2009:
1. Glycaemic control (measured as proportion of hyperglycaemic time, number of severe hypoglycaemic episodes per patient)
2. Effects on the somatotrophic axis

Initial information at time of registration:
Number of episodes of hypoglycaemia per unit length of stay in the ICU

Secondary outcome measures
Current information as of 23/07/2009:
1. Biochemical markers:
1.1. The number of patients undergoing a hypoglycaemic episode and the number of hypoglycaemic episodes whilst receiving the study protocol
1.2. The number of patients undergoing a hypokalaemic episode and the number of hypokalaemic episodes whilst receiving the study protocol
1.3. Plasma concentrations of IGF-1, IGF-2, IGFBP-1, IGFBP-3, GH at baseline and on days 3,5, 8 and 15 of ICU stay
1.4. Plasma concentrations of HDL, LDL, TG's, FFA's at baseline and at days 3, 5 and 8 and 15 of ICU stay
1.5. The difference between nitrogen excretion (as urinary urea) and nitrogen intake (as enteral or parenteral nutrition) on days 3, 5 and 8 of ICU stay
1.6. Plasma protein carbonyl quantification on days 1, 3, 5, 8 and 15 of ICU stay

2. Morbidity and mortality:
2.1. ICU length of stay
2.2. Antibiotic free days
2.3. 30 day mortality

3. Markers of protocol compliance:
3.1. Time-weighted average blood glucose concentration
3.2. Time-weighted average serum potassium concentration
3.3. Time-weighted average insulin infusion and total insulin delivered

Initial information at time of registration:
1. Biochemical markers:
1.1. The number of episodes of hypokalaemia per unit length of stay in the ICU
1.2. The plasma levels of IGF-1, IGFBP-1, IGFBP-3, ALS on days 1, 3, 5, 8 and 15 of ICU stay
1.3. The plasma HDL, LDL and triglycerides on days 1, 3, 5, 8 and 15 of ICU stay
1.4. The plasma levels of free fatty acids on days 1, 3, 5, 8 and 15 of ICU stay
1.5. The difference between nitrogen excretion (as urinary urea) and nitrogen intake (as enteral or parenteral nutrition) on days 1, 3, 5, 8 and 15 of ICU stay
1.6. Plasma protein carbonyl quantification on days 1, 3, 5, 8 and 15 of ICU stay

2. Surrogate markers for improved long term outcome:
2.1. ICU length of stay
2.2. Hospital length of stay
2.3. Antibiotic free days (as a measure of nosocomial infection)

3. Mortality:
3.1. ICU mortality
3.2. 30 day mortality
3.3. Hospital mortality

4. Markers of protocol compliance:
4.1. Time-weighted average blood glucose concentration
4.2. Time-weighted average serum potassium concentration
4.3. Time-weighted average insulin infusion and total insulin delivered

Overall study start date
01/07/2005

Completion date
30/06/2006

Eligibility

Key inclusion criteria
Current information as of 23/07/2009:
Adult patients likely to remain on the intensive care unit (ICU) for greater than 48 hours.

Initial information at time of registration:
Adult patients likely to remain on the intensive care unit (ICU) for greater than 5 days

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Patients known to have diabetes mellitus
2. Patients admitted with diabetic ketoacidosis
3. Patients with a current diagnosis of pancreatitis
4. Patients who have undergone hepato-biliary surgery in the current admission
5. Patients with an insulinoma or pituitary tumour
6. Patients currently on, or likely to require, total parenteral nutrition
7. Patients who are pregnant

8. Patients with a primary diagnosis of head injury
9. Patients with a primary diagnosis of intracranial haemorrhage
10. Patients with a primary diagnosis of stroke
11. Inclusion in another study
12. Patients currently placed under a section order
13. Patients with a learning disability
14. Patients/relatives unable to speak English and without a suitable translator
15. Patients already on higher than 4 units of insulin per hour and have been so for at least 3 out of the last 24 hours

Date of first enrolment
01/07/2005

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
Research & Development Department
Manor House
John Radcliffe Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
University/education

Funder Name
British Journal of Anaesthesia/Royal College of Anaesthetists (UK)

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?
Protocol article	protocol	08/03/2018		Yes	No