ISRCTN42412334 https://doi.org/10.1186/ISRCTN42412334

Intensive blood glucose control for chronic obstructive pulmonary disease (COPD) patients on acute medical wards

Submission date 01/10/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/11/2008	**Overall study status** Completed	
Last Edited 26/10/2011	**Condition category** Respiratory	

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
NCT00764556

Secondary identifying numbers
SGH-ClinPharm-1

Study information

Scientific Title
Phase II study: investigation of the safety and efficacy of a protocol for tight glycaemic control in patients with chronic obstructive pulmonary disease (COPD) exacerbations admitted to an acute medical unit

Acronym
IPS 2008

Study objectives
This study will test the safety and feasibility of tight control of blood glucose with insulin in patients with acute exacerbations of COPD outside the intensive care setting in acute medical wards.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint UCL/UCLH Ethics Committee gave approval in early 2008 (ref: 07/H0715/93)

Study design
Prospective, non-randomised, phase II study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Acute exacerbation of chronic obstructive pulmonary disease (AECOPD)

Interventions
This is a single arm trial. Patients receive insulin with the aim of controlling blood glucose to a target of 4.4 - 6.5 mM. Insulin is initially intravenous (actrapid), then subcutaneous (glargine or

detemir plus aspart). Patients receive insulin throughout hospital admission and is stopped on discharge. Follow up is during hospital stay; there is no follow up after discharge for the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The frequency of severe hypoglycaemia - neuroglycopaenic symptoms (other than mild agitation) responsive to administration of carbohydrate. The outcomes are measured/looked for continuously during treatment/hospital stay.

Secondary outcome measures
1. The frequency of symptomatic hypoglycaemia (capillary glucose less than or equal to 3.3 mM and symptoms consistent with hypoglycaemia)
2. The frequency of asymptomatic hypoglycaemia (capillary glucose less than or equal to 3.3 mM without any symptoms consistent with hypoglycaemia)
3. Mean 24 hour capillary glucose concentrations
4. Proportion of capillary glucose measurements in target range (4.4 - 6.5 mM)
5. Comparison of capillary blood glucose measurements to those obtained from the Guardian REAL®-time continuous glucose monitoring system
6. Comparison of rates of detection of hypoglycaemia by capillary and continuous blood glucose monitoring
7. Quantification of acceptability of the study intervention to patients

The outcomes are measured/looked for continuously during treatment/hospital stay.

Overall study start date
01/05/2008

Completion date
01/05/2009

Eligibility

Key inclusion criteria
1. Physician diagnosis of acute exacerbation of chronic obstructive pulmonary disease (AECOPD) as primary cause for admission
2. Able to enter study within 24 hours of admission
3. Age greater than 40 years, male and female

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
20

Key exclusion criteria
1. Intensive care unit admission
2. Moribund or not for active treatment
3. Admission expected to last less than 48 hours
4. Unable or unwilling to give informed consent
5. Known type I diabetes mellitus
6. Patients with reduced awareness of hypoglycaemia including reduced Glasgow Coma Scale or those taking beta blockers
6. Patients with renal or hepatic failure at increased risk of hypoglycaemia

Date of first enrolment
01/05/2008

Date of final enrolment
01/05/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Clinical Pharmacology
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's, University of London (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.sgul.ac.uk/

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - NIHR Trainees Programme funds academic clinical fellows

Funder Name
Own consumables

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	23/07/2011		Yes	No