

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
Registration date 20/11/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/10/2011	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Emma Baker

Contact details
Centre for Clinical Pharmacology
Room 66, Ground Floor Jenner Wing
St George's, University of London
Cranmer Terrace
London
United Kingdom
SW17 0RE
+44 (0)20 8725 5383
ebaker@sgul.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00764556

Protocol serial number
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)

Primary study design

Interventional

Study design

Prospective, non-randomised, phase II study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Centre for Clinical Pharmacology

London

United Kingdom

SW17 0RE

Sponsor information

Organisation

St George's, University of London (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

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