

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

<b>Submission date</b> 01/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2011	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## 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

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 - neuroglycopenic 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**

Cranmer Terrace

London

England

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SW17 0RE

**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?
<a href="#">Results article</a>	results	23/07/2011		Yes	No