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Metformin in chronic obstructive pulmonary disease

Submission date	Recruitment status	[_] Prospectively registered
18/01/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/02/2016	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-020818-28

ClinicalTrials.gov (NCT)
NCT01247870

Protocol serial number
10.0086

Study information

Scientific Title
A randomised, double-blind, placebo-controlled trial of metformin in chronic obstructive pulmonary disease (COPD) exacerbations: a pilot study evaluating anti-hyperglycaemic efficacy

Study objectives
That metformin is efficacious as a glucose-lowering agent among patients admitted to hospital for chronic obstructive pulmonary disease (COPD) exacerbation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 08/09/2010, ref: 10/H1102/62

Study design
Randomised multicentre double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
Active: metformin 1 g twice-daily for 28 - 35 days
Comparator: placebo capsules twice-daily for 28 - 35 days

Clinical follow-up is for 1 month (range 28 - 35 days) for both the active and placebo arms.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome(s)
Mean capillary glucose concentration from study entry to hospital discharge

Key secondary outcome(s))
Current secondary outcome measures as of 06/03/2014:
1. COPD Assessment Test score, measured at study entry, hospital discharge and follow-up
2. Exacerbation of Chronic Pulmonary Disease Tool (EXACT) score, measured at days 5, 10 and 28

3. Number of days from hospital admission to hospital discharge
4. Recurrent exacerbation, readmission and death rate, measured at 3 months
5. Insulin requirement during hospitalisation period, measured during hospitalisation period following study entry
6. Haemoglobin A1c, measured at follow-up (one month post study entry)
7. C-reactive protein concentration, measured at days 7 and follow-up (one month)
8. Body mass index, measured at follow-up (one month)
9. Waist circumference, measured at follow-up (one month)
10. Forced expiratory volume in 1 second, measured at at hospital discharge and follow-up (one month)
11. Serum fructosamine concentration at discharge and one month
12. Inflammatory cytokine concentrations and markers of oxidative stress at discharge and one month

Previous secondary outcome measures:
1. COPD Assessment Test score, measured at study entry, hospital discharge and follow-up
2. Exacerbation of Chronic Pulmonary Disease Tool (EXACT) score, measured at days 5, 10 and 28
3. Number of days from hospital admission to hospital discharge
4. Recurrent exacerbation, readmission and death rate, measured at 3 months
5. Insulin requirement during hospitalisation period, measured during hospitalisation period following study entry
6. Haemoglobin A1c, measured at follow-up (one month post study entry)
7. C-reactive protein concentration, measured at days 7 and follow-up (one month)
8. Body mass index, measured at follow-up (one month)
9. Waist circumference, measured at follow-up (one month)
10. Forced expiratory volume in 1 second, measured at at hospital discharge and follow-up (one month)
11. Response to cutaneous steroid application (McKenzie test), measured at study day greater than or equal to 5

Completion date
01/07/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/03/2014:
1. Pre-existing diagnosis of COPD
2. Admission to hospital principally for an exacerbation of COPD
3. Aged greater than or equal to 35 years
4. Expected to remain in hospital for ≥48 hours

Previous inclusion criteria:
1. Pre-existing diagnosis of COPD
2. Admission to hospital principally for an exacerbation of COPD
3. Aged greater than or equal to 35 years
4. Able to enter the study within 48 hours of admission

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Prior diagnosis of diabetes mellitus requiring insulin or oral hypoglycaemic therapy
2. Hypersensitivity to metformin hydrochloride or to any of the excipients
3. Renal impairment
4. Severe sepsis
5. Metabolic acidosis
6. Decompensated type 2 respiratory failure
7. Severe congestive cardiac failure
8. Acute coronary syndrome
9. Hepatic insufficiency
10. Excessive alcohol consumption
11. Malnourished or at high risk for malnutrition
12. Moribund or not for active treatment
13. Admitted to critical care unit
14. Unable to give informed consent
15. Pregnancy or lactation

Date of first enrolment
24/01/2011

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's, University of London
London
United Kingdom
SW17 0RE

Sponsor information

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

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

Funder Name
British Lung Foundation (UK) (ref: COPD10/7)

Alternative Name(s)
BLF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Medical Research Council (UK) (ref MR/J010235/1)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/07/2016		Yes	No
HRA research summary			28/06/2023	No	No