Metformin in chronic obstructive pulmonary disease

Submission date	Recruitment status No longer recruiting	Prospectively registered		
18/01/2011		☐ Protocol		
Registration date 17/03/2011	Overall study status Completed	Statistical analysis plan		
		[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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2010-020818-28

IRAS number

ClinicalTrials.gov number

NCT01247870

Secondary identifying numbers

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

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 below to request a patient information sheet

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 measure

Mean capillary glucose concentration from study entry to hospital discharge

Secondary outcome measures

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
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- 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

Overall study start date

24/01/2011

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

Age group

Adult

Sex

Both

Target number of participants

69

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

England

United Kingdom

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

Sponsor information

Organisation

St George's, University of London (UK)

Sponsor details

Joint Research Office (mail point H0A) Cranmer Terrace London England United Kingdom SW17 0RE +44 (0)20 8725 4986 research@sgul.ac.uk

Sponsor type

University/education

Website

http://www.sgul.ac.uk/research/about-research-at-st-georges

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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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