

# Does oral creatine supplementation enhance recovery from a worsening of chronic bronchitis?

<b>Submission date</b> 03/08/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/06/2017	<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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
RN06NT003

# Study information

## Scientific Title

Does oral creatine supplementation enhance recovery from chronic obstructive pulmonary disease (COPD) exacerbation?

## Study objectives

In patients with chronic obstructive pulmonary disease (COPD) exacerbation, supplementation with 5 g of creatine monohydrate three times daily prevents loss of, or increases, fat free mass after 14 days of treatment when compared to placebo.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Glasgow East LREC, 24/08/2006, ref: 06/50704/45

## Study design

Randomised stratified double-blind placebo-controlled study

## 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 to request a patient information sheet

## Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

## Interventions

The study will have two arms:

### 1. Standard care with placebo:

This will comprise best clinical practice defined by National Institute for Clinical Excellence (NICE) (Clinical Guideline 12: "Management of chronic obstructive pulmonary disease in adults in primary and secondary care." February 2004). Placebo consists of 5 g lactose mixed with 30 g glucose monohydrate, given mixed with hot water as a drink, three times a day.

### 2. Standard care with creatine:

This will comprise best clinical practice defined by NICE (Clinical Guideline 12: "Management of

chronic obstructive pulmonary disease in adults in primary and secondary care." February 2004). Creatine supplementation is given as 5 g of creatine monohydrate mixed with 30 g glucose monohydrate, given mixed with hot water as a drink, three times a day. There is evidence that concomitant administration of glucose increases muscle uptake of creatine.

Patients will receive the investigational supplement for 14 days (42 doses).

Details of investigational supplement:

Creatine is naturally found in the body and is present in the diet in fish and meat (herring contains 6.5 - 10 g creatine per kg). Approximately 50% of total body creatine is provided by the diet with the rest produced endogenously from the amino acids arginine, glycine and methionine in the liver and kidneys. The majority of body creatine is stored in skeletal muscle, where the creatine transporter protein moves creatine across the plasma membrane from the blood against a large concentration gradient. Creatine spontaneously degrades to creatinine, which is excreted by the kidneys. Creatine is rapidly phosphorylated to phosphocreatine which provides essential energy to exercising muscle via re-phosphorylation of adenosine diphosphate (ADP) to adenosine triphosphate (ATP).

### **Intervention Type**

Supplement

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Creatine supplementation

### **Primary outcome measure**

Fat free mass, measured at baseline and after treatment (2/52; or 42 doses)

### **Secondary outcome measures**

1. Anthropometry
2. Hand-grip and strength
3. Maximal expiratory pressure (MEP)/maximal inspiratory pressure (MIP)/sniff nasal inspiratory pressure (SNIP)
4. Rise to go test
5. Six minute walk test (SMWT)
6. High sensitivity C-reactive protein (hsCRP)
7. Interleukin-six (IL-6)
8. Tumour necrosis factor-alpha (TNF- $\alpha$ )
9. Digit span
10. Medical Research Council (MRC) dyspnoea scale
11. Hospital Anxiety and Depression (HAD) score
12. London Chest Activity of Daily Living (LCADL) score
13. Baseline/Transition Dyspnoea Index (BDI/TDI)

All endpoints measured at baseline and after treatment (2/52; or 42 doses)

### **Overall study start date**

29/05/2007

**Completion date**

29/05/2008

## Eligibility

**Key inclusion criteria**

1. Chronic obstructive pulmonary disease (COPD)
2. Acute exacerbation COPD

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

60

**Key exclusion criteria**

1. Alternative diagnosis for acute presentation
2. Active cardiac, neurological, neoplastic disease
3. Diabetes
4. Significant locomotor disease
5. Renal or hepatic impairment
6. Persisting decompensated respiratory acidosis
7. Depressed cognitive function
8. Terminal condition
9. Pregnant, lactating, or wish to become pregnant
10. Implanted cardiac pacemaker resynchronise or defibrillator device
11. Enteral route contraindicated

**Date of first enrolment**

29/05/2007

**Date of final enrolment**

29/05/2008

## Locations

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**University of Glasgow**  
Glasgow  
United Kingdom  
G31 2ER

## **Sponsor information**

### **Organisation**

University of Glasgow (UK)

### **Sponsor details**

Research and Enterprise  
University Avenue  
Glasgow  
Scotland  
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G12 8QQ

### **Sponsor type**

University/education

### **Website**

<http://www.gla.ac.uk/>

### **ROR**

<https://ror.org/00vtgdb53>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Chief Scientist Office (UK) (ref: CZG/2/261)

### **Alternative Name(s)**

CSO

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Local government

**Location**

United Kingdom

**Funder Name**

Glasgow Royal Infirmary (UK) - Endowment Fund (ref: 06Ref004 CH02 - Mullan)

## 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="#">Thesis results</a>	results	07/01/2013		No	No