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

Submission date 03/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/03/2008	**Overall study status** Completed	
Last Edited 08/06/2017	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised stratified double-blind placebo-controlled study

Study type(s)
Treatment

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

Key secondary outcome(s)
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-α)
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)

Completion date
29/05/2008

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

Scotland

Study participating centre
University of Glasgow
Glasgow
United Kingdom
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Sponsor information

Organisation
University of Glasgow (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

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?
Thesis results	results	07/01/2013		No	No