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

ng [] Protocol
us [] Statistical analysis
[X] Results
ry [_] Individual participa

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Prof Michael Lean

Contact details

Dept. of Human Nutrition University of Glasgow **Glasgow Royal Infirmary** Glasgow United Kingdom G31 2ER

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers RN06NT003

stered

plan

nt data

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-a)
- 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 United Kingdom 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?
Thesis results	results	07/01/2013		No	No