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Impact of smoking cessation on skeletal muscle

Submission date	Recruitment status	[ ] Prospectively registered
14/07/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/07/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/01/2020	Musculoskeletal Diseases	[ ] Record updated in last year

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
8238

Study information

Scientific Title

Impact of smoking cessation on skeletal muscle atrophy and hypertrophy pathways in chronic obstructive pulmonary disease (COPD)

Study objectives
Our hypothesis is that smoking cessation in patients with chronic obstructive pulmonary disease (COPD) will lead to an increase in skeletal muscle bulk and endurance and that this will be associated with alterations in the pathways controlling skeletal muscle atrophy and hypertrophy including the Akt/FOXO/atrogene, mTOR and MyoD and myostatin pathways. We also propose that smoking cessation will lead to a more oxidative fibre type with an increase in the expression of type I myosin and reduction in the expression of type II myosin heavy chains. We will investigate this by making detailed assessment of skeletal muscle function and examining biopsies from the quadriceps muscle before and after smoking cessation.

In parallel with this we will study the effect of smoking cessation on lung function, exercise capacity and systemic inflammation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCLH Committee Alpha approved, ref: 09/H0715/37

Study design
Single-centre observational non-randomised diagnosis and screening cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Effect of smoking cessation on skeletal muscle strength in people with chronic obstructive pulmonary disease (COPD) and in smokers with normal lung function

Interventions
Smoking cessation advice, counselling and pharmacotherapy as clinically indicated. This may include NRT and varenicline. Outcomes will be assessed 8 weeks after the quit date.

Intervention Type
Mixed

Primary outcome measure
Current primary outcome measure as of 18/10/2019:
Dynamic hyperinflation during cycle ergometry measured at 8 weeks after quit date

Previous primary outcome measure:
Activity of the IGF-1 PI3K/Akt/FOXO/atrogene pathway and the mTOR pathway in muscle biopsy specimens, measured at 8 weeks after quit date

Secondary outcome measures
Current secondary outcome measures as of 18/10/2019:
Measured at 8 weeks after quit date:
1. Quadriceps endurance
2. Quadriceps strength

Previous secondary outcome measures:
Measured at 8 weeks after quit date:
1. Dynamic hyperinflation during cycle ergometry
2. MyoD and myostatin protein and mRNA levels
3. Quadriceps endurance
4. Quadriceps strength

Overall study start date
01/11/2009

Completion date
01/10/2020

Eligibility

Key inclusion criteria
1. Consenting adult smokers who wish to quit
2. Both COPD patients who smoke and smokers with normal lung function
3. Male and female, lower age limit of 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 95; UK sample size: 95

Key exclusion criteria
The presence of significant co-morbidity judged likely to have a significant impact on muscle strength

Date of first enrolment
01/11/2009

Date of final enrolment
01/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Brompton Hospital
London
United Kingdom
SW3 6NP

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Imperial College
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other