

Impact of smoking cessation on skeletal muscle

Submission date 14/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/01/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Nick Hopkinson

Contact details

Royal Brompton Hospital
Fulham Road
London
United Kingdom
SW3 6NP

-
n.hopkinson@imperial.ac.uk

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