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Markers for emphysema versus airways disease in chronic obstructive pulmonary disease (COPD)

Submission date
21/05/2010

Recruitment status
No longer recruiting

Registration date
21/05/2010

Overall study status
Completed

Last Edited
27/09/2018

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
5323

Study information

Scientific Title
Markers for emphysema versus airways disease in chronic obstructive pulmonary disease (COPD)

Acronym
Markers for Emphysema versus Airways disease in COPD

Study objectives
Our hypothesis is that the mechanisms leading to emphysema and airway disease are distinct with respect to the type of inflammatory response in terms of genetic predisposition. The differential pathogenesis for emphysema and inflammatory airway disease entails that the two forms of COPD are linked to different markers at the DNA, RNA and protein level.

The project aims at identifying these markers. The markers will be elements involved in a differential pathogenesis for the different disease processes in COPD. They can be used for diagnostic approaches and therapeutic targets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 08/H0402/19)

Study design
Multicentre non-randomised observational prevention and cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Respiratory; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
1. Blood sample
2. Bronchoscopy

3. Computed tomography (CT) Scan
4. Lung samples
5. Sputum collection

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To use CT scanning to identify patients with COPD with predominant airway wall changes

Secondary outcome measures
1. Development of new diagnostic tools and to new therapies for COPD
2. Understanding differences in pattern of inflammation and genetic predisposition

Overall study start date
01/04/2008

Completion date
31/03/2011

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Child

Sex
Not Specified

Target number of participants
Planned sample size: 1000; UK sample size: 600

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/04/2008

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medicines Evaluation Unit Ltd
Manchester
United Kingdom
M23 9QZ

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Leicester Royal Infirmary
Infirmary Square
Leicester
England
United Kingdom
LE1 5WW

Sponsor type
Hospital/treatment centre

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
European Commission (Belgium)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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?
Protocol article	protocol	01/10/2012		Yes	No
Results article	results	01/07/2016		Yes	No