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Healthy volunteer bronchoscopy study

Submission date
06/12/2011

Recruitment status
No longer recruiting

Registration date
25/01/2012

Overall study status
Completed

Last Edited
10/12/2019

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A cough is a common problem for which people seek medical advice from their doctor or a respiratory (lung) specialist. It is thought that people who develop a chronic cough have very sensitive airways and cough medicines often do not help to relieve the cough. The reason behind this is not fully understood. The purpose of this study was to collect samples from healthy volunteers in order to compare them to patients with chronic cough. This research may be able to help us understand why people with a chronic cough have sensitive airways. In order to draw conclusions from bronchoscopy data from patients with chronic cough we needed to establish findings in healthy non-smoking, non-coughing individuals, in whom there was no suggestion of asthma, postnasal drip (mucus dripping down the throat from the back of the nose), or gastro-oesophageal reflux (where stomach acid leaks out of the stomach and into the gullet) - the common causes of chronic unexplained cough.

Who can participate?
We were looking for adults (18 years and over) who were non-smokers with no history of chronic illness and who had not a chest infection, cough or cold in the last four weeks.

What does the study involve?
The study involved two visits to the hospital. At visit 1, participants were seen by a study doctor who took a medical history and carried out a physical examination. If they were on any medications we asked that they be brought in so that they could be noted down by the doctor (participants were not asked to stop taking any medications). All participants were asked to undergo the same tests and received the same treatment. Visit 1 included spirometry (a lung function test), a methacholine challenge test (a test for asthma), skin prick allergy testing and a blood test.
Visit 2 involved having a bronchoscopy. A bronchoscopy is a diagnostic procedure in which a small tube with a camera on the end is inserted through the nose and down into the lungs. This provides a view of the airways and allows sampling.

What are the possible benefits and risks of participating?
As healthy volunteers, it was unlikely that they would benefit directly from this research. It was possible that some of the tests carried out gave them unexpected information (for example about allergies) which they did not know. This may, or may not, have been helpful. We were happy to give them additional care or advice on the results of these tests. Participants were

made aware that if any of these tests had significant and unexpected results, they would be told about this, and referred to a specialist where needed as part of our duty of care. We were not able to keep this information from them, even if they would prefer not to know.
We advised that a friend or relative accompanied the participants and that a responsible person stayed with them for the next 24 hours. They were advised not to drive, operate machinery, sign legal documents, or consume alcohol for 24 hours.
Our screening tests were routine and very safe. Participants may have experienced a slight twitching, the need to cough, or a tight feeling in their chest during the asthma (methacholine challenge) test. This was easily reversed using an inhaler.
Participants may have experienced a red itchy patch on their skin from the allergy (skin prick) test. This would have faded quickly and if necessary we were able to provide antihistamine cream to prevent the itch.
During the blood test, they may have experienced slight discomfort (a sharp scratch) at the time and occasionally a small bruise would be caused at the point where the needle pierced the skin.
Bronchoscopy is generally a safe and well tolerated procedure; the main risks are local discomfort to the throat (minimised by use of local anaesthetic) and some patients experience a small amount of bleeding from biopsy sites. The bronchoscopy itself is not painful but participants were able to rest in the department for a few hours to allow the medications to wear off. After one to two hours, normal eating and drinking is allowed once throat numbness has worn off but the throat may feel a little scratchy for a few days.
There was a theoretical risk of infection but all equipment was sterilised prior to use.
There was a small risk of low blood oxygen levels and disordered heart beat. There was continuous monitoring throughout the procedure and if this was to occur the examination would be discontinued and immediate treatment given.
The medication used in sedation can occasionally cause nausea, breathing problems or altered blood pressure. This can be rapidly reversed using an antidote for the sedation. The antidote was on hand in the department.

Where is the study run from?
This was a single centre study carried out at the North West Lung Research Centre, University Hospital of South Manchester, Manchester, UK.

When is the study starting and how long is it expected to run for?
The study started in May 2007 and completed recruitment in October 2007.

Who is funding the study?
This study was funded by the North West Lung Centre charity research fund.

Who is the main contact?
Dr Jaclyn Smith
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Contact information

Type(s)
Scientific

Contact name
Dr Jaclyn Smith

Contact details

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United Kingdom
M23 9LT

Additional identifiers

Study information

Scientific Title
Bronchoalveolar lavage and biopsy findings in healthy non-smoking individuals

Study objectives
In order to draw any robust conclusions from bronchoscopy data on patients with chronic cough we need to establish normal ranges for lavage and biopsy findings in 'healthy' non-smoking, non coughing individuals, in whom there is no suggestion of asthma, postnasal drip or gastro-oesophageal reflux (the common causes of chronic unexplained cough)

In chronic cough there is particular interest in both the inflammatory cells found lining the small airways (obtained at lavage) and amount of inflammation seen within the more proximal airway wall (biopsy). Whether inflammation seen is indicative of the aetiology of cough, or a consequence of repearted trauma to thte airways induced by presistent cough, is unclear and further work is required to establish this.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study was approved by North Manchester Research Ethics Committee in April 2007 (REC Ref: 07/Q1406/15

Study design
Single centre cross sectional clinical trial

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Chronic cough

Interventions
1. Blood test
2. Pulmonary funciton test
3. Skin prick allergy test

4. Methacholine challenge (bronchial hyper-reactivity test)
24 hours after the bronchoscopy patients will be contacted by telephone to ascertain that no adverse effects have occurred and that no questions have arisen

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Presence or absence of airway inflammation in healthy volunteers

Key secondary outcome(s))
1. Lymphocyte count in healthy volunteers of different ages/sex
2. Presence/absence of pepsin in lavage of healthy volunteers
3. Airway wall histology in healthy volunteers
4. Evidence of allergy (Immunoglobulins)
5. Provision of a bank of biopsy and lavage samples from healthy volunteers for use in future research into airway wall remodelling

Completion date
31/10/2007

Eligibility

Key inclusion criteria
1. Over 18 years of age
2. Normal lung function
3. Negative methacholine challenge (no bronchial hyper-reactivity)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria

1. Recent upper respiratory infection (<4 weeks)
2. Pregnancy / breast feeding
3. Use of inhaled or oral steroids in last three months
4. History of drug or alcohol abuse
5. Chronic respiratory, cardiovascular, gastro-intestinal, haematological, neurological or psychiatric illness or chronic ill health. This includes past histroy at any age of asthma, or current symptomatic rhinitis
6. Symptomatic gastro-oesophageal reflux or post nasal drip, or history of chronic cough
7. History of auto-immunity/diabetes mellitus
8. Current smoker
9. Ex-smoker of < 6 months or >10 pack/year history
10. History of anaphylaxis or known allergy to lignocaine/midazolam/methacholine

Date of first enrolment
01/05/2007

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Respiratory Research
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust (UK)

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
North West Lung Centre Charity (UK)

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?
Results article	results	14/09/2012	10/12/2019	Yes	No