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Citric acid cough challenge validation

Submission date 05/06/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/09/2009	**Overall study status** Completed	
Last Edited 25/09/2012	**Condition category** Signs and Symptoms	

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
AcadMed CTU04/05

Study information

Scientific Title
Validation of the citric acid cough challenge using the KoKo DigiDoser system in healthy volunteers: a 4-week randomised single centre crossover study

Study objectives
The citric acid cough challenge was first reported in humans over 50 years ago. The test was established to allow for the quantification of cough and also as a tool for the assessment of antitussive properties of certain therapies. Since this time many different protocols have been published to measure cough reflex sensitivity these can vary in terms of the nebuliser used, tussive agent, single breath, single dose, dose response and number of coughs required to attain a threshold. In our opinion a definitive method for measuring cough sensitivity needs to be established to allow for standardisation of results from different groups to be compared. The standardisation of this test will lead to a higher quality of research, better drug development and ultimately better patient care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding Local Research Ethics Committee approved on the 26th April 2006 (ref: 06 /Q1104/46)

Study design
Randomised single centre crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Artificially induced cough

Interventions
Volunteers were randomised for the order methods to induce artificial cough, i.e., whether the Mefar dosimeter was used first or the KoKo DigiDoser.

The following assessments were then performed:
1. Impulse oscillometry
2. Spirometry
3. Citric acid cough challenge

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Reproducibility of cough reflex sensitivity to citric acid (measured via inhalation of incremental, doubling concentrations of citric acid until the concentration inducing two or more coughs or five or more coughs is reached)using the modified Devilbiss 646 nebuliser powered by the KoKo DigiDoser. Measured within 1 day comparing baseline challenge and challenges at 1, 2 and 4 hours post-baseline to measure within-day reproducibility.

Secondary outcome measures
To compare the reproducibility of cough reflex sensitivity using the modified Devilbiss 646 nebuliser powered by the KoKo DigiDoser with that of the more commonly used MB2 nebuliser powered by the MB3 mefar dosimeter. Assessed at baseline and then two weeks later to assess between-day reproducibility.

Overall study start date
04/07/2006

Completion date
19/10/2006

Eligibility

Key inclusion criteria
1. Healthy male/female volunteers
2. Male and female subjects of at least 18 years of age
3. Non-smokers or, ex-smokers of at least 12 months
4. Forced expiratory volume in one second (FEV1) greater than 80% of predicted

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Female subjects who are pregnant, or lactating, or who are of child bearing potential but are not using contraceptive measures
2. Suffering from any active seasonal allergies
3. Suffering from concomitant disease which may interfere with study procedures or evaluation.
4. Subjects suffering from gastroesophageal reflux taking proton pump inhibitors or any other regular antacid therapy
5. Subjects suffering from post nasal drip syndrome
6. A recent respiratory tract infection within 6 weeks prior to entry on to study
7. Use of medications known to alter the cough reflex
8. Smoking history of greater than 10 pack years

Date of first enrolment
04/07/2006

Date of final enrolment
19/10/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Respiratory Medicine
Cottingham
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Research and Development Office
Medical Research and Teaching Centre
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Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Hull and East Yorkshire Hospitals NHS Trust (UK) - Research and Development Grant

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?
Results article	results	10/08/2010		Yes	No