Citric acid cough challenge validation

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 Daisy Building Castle Hill Hospital Castle Road Cottingham England United Kingdom HU16 5JQ +44 (0)1482 461883 James.Illingworth@hey.nhs.uk

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