

Treatment trial of high altitude cough

Submission date 01/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/07/2010	Condition category Respiratory	<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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

077078; OUCRU # 17AV; B9RJIXO

Study information

Scientific Title

Treatment of high altitude cough (HAC) with salmeterol 50 µg and fluticasone 250 µg, one puff twice daily (bid) on Mount Everest: a randomised controlled trial

Acronym

17AV

Study objectives

In this study we want to test the hypothesis that inhaled salmeterol and fluticasone will be effective in the treatment of high altitude cough (HAC) in climbers at the base camp or while climbing Everest.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxford Tropical Research Ethics Committee (UK) approved on the 10th February 2010 (ref: 09-10)

Study design

Single centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

High altitude cough (HAC)

Interventions

Please note that as of 30/07/10 this trial has been extended from 01/10/2010 to 01/10/2011

The study will take place in the Everest base camp (5300 m).

Mountaineers as they ascend to base camp will be made aware of this study by means of recruitment posters in the lodges that provide accommodation in the villages along the way to the Everest Base Camp and also by requests for volunteers at the daily altitude education talks given at the Himalayan Rescue Association post in Pheriche.

Interested mountaineers will have the study explained again by the Base Camp Clinic doctors and asked if they would like to participate. Study staff will ensure that participants do not meet any of the exclusion criteria.

Participants who consent will be assigned a study number and then requested to fill out a baseline modified Leicester Cough Questionnaire. They will also have their blood pressure, pulse, peak flow, O2 saturation measured and lung and heart auscultation carried out.

Participants will then be randomised by computer program to either arm of the study:

1. Inhaled (through a rotahaler) salmeterol 50 µg and fluticasone 250 µg puffs twice daily (bid)
2. Placebo bid

The rotahalers have a 14 day supply of drugs. Their randomisation number will correspond to prepackaged identical rotahalers.

At day 7 and day 14, the subjects will again be re-assessed using the above parameters and again filling out the modified Leicester Cough Questionnaire. Unused medication will be collected and disposed of according to local regulations.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Salmeterol, fluticasone

Primary outcome measure

The incidence of HAC using the modified the Leicester Cough Questionnaire before and after the rotahaler intervention. Measured at day 0, day 7 and day 14 of the study.

Secondary outcome measures

Measured at day 0, day 7 and day 14 of the study:

1. Oxygen saturation
2. Peak flow
3. Pulse
4. Lung auscultation

Overall study start date

01/04/2010

Completion date

01/10/2011

Eligibility

Key inclusion criteria

1. Healthy men or women
2. Between the ages of 18 and 65 years
3. Have HAC, defined as persistent (greater than 1 day) sometimes paroxysmal cough that disturbs sleep or daily activity or both. The cough may be dry or productive but is not associated

with fever, chills, shortness of breath or desaturation less than 75% at Everest Base Camp (EBC) (5300 m).

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

72

Key exclusion criteria

1. Individuals with other obvious diagnoses causing cough (e.g., viral or bacterial pneumonia, high altitude pulmonary oedema [HAPE])
2. Unwillingness to comply with study treatment
3. Lack of informed consent
4. Individuals on beta agonists or steroid inhalers, steroid nasal sprays or oral steroids within the last 2 weeks

Date of first enrolment

01/04/2010

Date of final enrolment

01/10/2011

Locations**Countries of recruitment**

Nepal

Study participating centre

Lal Durbar

Kathmandu

Nepal

44600

Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

Centre for Tropical Medicine, CCVTM
Churchill Hospital
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LJ

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)**Funder type**

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 077078)

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