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Treatment trial of high altitude cough

Submission date 01/03/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 16/04/2010	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 30/07/2010	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Buddha Basnyat

Contact details
Lal Durbar
GPO Box 3596
Kathmandu
Nepal
44600

Additional identifiers

Protocol serial number
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 flucatisone 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)

Primary study design
Interventional

Study design
Single centre randomised controlled trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
Measured at day 0, day 7 and day 14 of the study:
1. Oxygen saturation
2. Peak flow
3. Pulse
4. Lung auscultation

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

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)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration