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The SPironolactone and ACEtazolamide (SPACE) trial in the prevention of acute mountain sickness

Submission date 30/07/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/11/2008	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

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
OXTREC 1

Study information

Scientific Title

Acronym
SPACE

Study objectives
Acute Mountain Sickness (AMS) is like a hangover (headache, nausea and tiredness being prominent features) that may manifest at altitudes greater than 2600 m when people ascend too high too fast.

This is a study to ascertain the benefit of spironolactone (aldactone), a water pill, in the prevention of AMS which comprises of headache, nausea and tiredness at altitude greater than 2700 m. Acetazolamide (Diamox®) which we know works for the prevention of AMS will be compared with spironolactone and a placebo or a sugar pill.

Hypothesis:
Spironolactone will prevent AMS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 24/11/2008: OXTREC approval on 07/10/2008 for the study (031 07).

Study design
Randomised, double blind, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Acute mountain sickness

Interventions

This is a prospective three armed, double blind, randomised, placebo controlled trial. Computer generated randomisation of spironolatone, acetazolamide and placebo will be carried out. After consent is obtained, participants will receive a four days supply of either spironolactone 50 mg twice daily (bid), acetazolamide 250 mg bid or visually matched placebo bid. Trekkers will be enrolled in the study and baseline measurements done at Pheriche (4300 m) and reassessed after their arrival at the endpoint in Lobuje (5000 m). The reassessment will take place at least 36 hours to a maximum of 96 hours (4 days) after taking the study drug.

Assessments and measurements will be made in these areas prior to and after ascension on the study drug:
1. Lake Louise Questionnaire
2. Oxygen saturation via pulse oximetry

The approach to Everest Base Camp provides a unique study population for the following reasons:
1. Large numbers of recently arrived (non-acclimated) trekkers
2. Relatively homogenous population (gender, age, physical fitness, etc.) with relatively few pre-existing conditions
3. Linear population movement along the approach
4. Rapid and quantitatively large elevation change (about 700 m)

Data will also be collected on the demographics of the study population at the enrolment site. The study will not provide financial assistance in the event of the development of complications of being at high altitude.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Spironolactone, acetazolamide

Primary outcome measure
Main outcome measure will be incidence of AMS measured by Lake Louise acute mountain sickness score (LLscore) greater than or equal to three with headache and at least one other symptom.

Outcomes will be measured at baseline (Pheriche 4300 m) and remeasured at Lobuje (5000 m). The reassessment will take place at least 36 hours to a maximum of 96 hours (four days) after taking the study drug.

Secondary outcome measures
1. Oxygen saturation measured by pulse oximeter
2. Severity of symptom (LLscore greater than five)
3. Incidence of headache and severity of headache

Outcomes will be measured at baseline (Pheriche 4300 m) and remeasured at Lobuje (5000 m). The reassessment will take place at least 36 hours to a maximum of 96 hours (four days) after taking the study drug.

Overall study start date
10/10/2007

Completion date
25/11/2007

Eligibility

Key inclusion criteria
1. Healthy subjects between the ages of 18 and 65
2. Male or female
3. Non-Nepali
4. Without AMS or any concurrent illness
5. Not already taking acetazolamide or any other drug for the prevention of altitude illness

Subjects will be enrolled by study administrators en route directly to Everest Base Camp or Kala Patthar between the villages of Pheriche/Dingboche and Lobuje.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
100 in each arm of the study

Key exclusion criteria
1. Individuals not meeting inclusion criteria, including mild AMS (more than one mild symptom on the Lake Louise Questionnaire) or significantly depressed oxygen saturation (less than 75%)
2. Females known to be pregnant, or cannot exclude the possibility of being pregnant, or have missed menses by over seven days
3. Individuals with a known drug allergy to acetazolamide or other sulfa drugs
4. Individuals who are on Angiotensin-Converting Enzyme (ACE) inhibitors (like enalapril) or other diuretics like amiloride or triamterene, as concurrent administration with spironolactone can cause hyperkalemia
5. Individuals who have spent 24 hours at an altitude of 4500 metres/14,000 feet within the last nine days
6. Anyone known to have taken any of the following in the last two days:
6.1. Acetazolamide (Diamox®)
6.2. Steroids (dexamethasone, prednisone)
6.3. Theophylline
6.4. Diuretics (Lasix®)
7. Individuals who have a known intracranial space occupying lesion or a history of elevated

intracranial pressure, (i.e. tumours, hydrocephalus, etc)
8. Lack of informed consent will obviously mandate exclusion

Date of first enrolment
10/10/2007

Date of final enrolment
25/11/2007

Locations

Countries of recruitment
Nepal

Study participating centre
Nepal International Clinic
Kathmandu
Nepal
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Sponsor information

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Sponsor type
University/education

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Funder(s)

Funder type
Research organisation

Funder Name
Oxford University Clinical Research Unit (Vietnam) (ref: HB0075)

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