ISRCTN91790322 https://doi.org/10.1186/ISRCTN91790322

Altitude Sickness in Climbers and Efficacy of Non-steroidal anti-inflammatory drugs (NSAIDs) Trial

Submission date
19/09/2008

Registration date
22/09/2008

Last Edited
15/01/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acute mountain sickness (AMS) is a common problem in people traveling higher than 2000 m in elevation. AMS involves headache, loss of muscle control, and can lead to brain swelling that causes death. Acetazolamide is a drug currently used to treat AMS. Recent research has shown that Ibuprofen may also prevent or reduce AMS. The goal of the study is to determine whether ibuprofen prevents AMS more effectively than current treatment.

Who can participate?
The study plans to enrol 350 non-Nepali male and female trekkers passing through the villages of Pheriche or Dingboche between the ages of 18-65, without headache and not already taking ibuprofen.

What does the study involve?
Trekkers will be recruited as they travel from either Pheriche or Dingboche on their way to Lobuje. They will be randomly allocated to take either ibuprofen or placebo (dummy) capsules. They will take the medication 18-24 hours prior to beginning their climb. Basic measurements will be taken before trekkers begin their climb, such as pulse rate, and an AMS questionnaire will be administered. After reaching the destination of Lobuje, the measurements will be taken again, and the AMS questionnaire will be administered again.

What are the possible benefits and risks of participating?
Participants may receive better treatment than standard care by participating in this study. The likelihood of a severe reactions to ibuprofen is uncommon, and participants will be removed from the study and provided with treatment if such a reaction occurs.

Where is the study run from?
The study is run by researchers at the Oxford University Clinical Research Unit (OUCRU) Nepal; The Nepal International Clinic Kathmandu, Nepal.

When is the study starting and how long is it expected to run for?
The study ran from October to November 2008.

Who is funding the study?
The Wellcome Trust (UK).

Who is the main contact?
The Clinical Trials Unit at the Oxford University Clinical Research Unit Viet Nam
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ctu05avjul08

Study information

Scientific Title
Randomised, double blind placebo controlled trial comparing Ibuprofen 600 mg three times per day versus placebo in the prevention of acute mountain sickness

Acronym
ASCENT

Study objectives
Ibuprofen 600 mg twice daily (TID) given at least 18 - 24 hours in advance of ascent will be superior to placebo in decreasing both the incidence and severity of acute mountain sickness (AMS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Tropical Medicine Research Ethics Committee (OXTREC) (UK), pending as of 19/09/2008. Submitted for review on the 25/09/2008.

Study design
Prospective double-blind randomised placebo-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 headache (HAH) and acute mountain sickness (AMS)

Interventions
Ibuprofen 600 mg TID given at least 18 - 24 hours in advance of ascent, versus placebo. Participants will begin the study capsules 18 - 24 hours before they leave from Pheriche (4280 m) or Dingboche (4358 m), in order to reveal any significant acute adverse reactions before they leave for higher altitude; amounting to three doses before ascent. In the highly unlikely event of an adverse reaction, the participant will be in close proximity to study administrators and the Himalayan Rescue Association aid post, where the code can be broken for medical evaluation. Most participants will only take part of one day to arrive at the endpoint of Lobuje (4950 m), whereas some participants will stop at an intermediate altitude before ascending. Otherwise healthy participants without adverse reactions will continue on to the village of Lobuje, where they will again be evaluated on the first night of their arrival and the morning after (LLQ, visual analogue scale [VAS], pulse oximetry, intraocular ultrasound, ascent profile, infectious symptoms, side effects data, and compliance). After data collection the study will be completed for each participant.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Ibuprofen

Primary outcome measure
A diagnosis of AMS on the LLQ requires a score of three or greater with the mandatory presence of headache and at least one of the following symptoms: dizziness or light-headedness, fatigue, gastrointestinal (GI) symptoms (nausea/vomiting), or difficulty sleeping.

Secondary outcome measures
1. Oxygen saturation has a rough correlation with AMS symptoms, and will be measured with the use of a pulse oximeter, which is validated for use at high altitude (Nonin Onyx, Nonin Medical Products, Minneapolis, MN)
2. HAH incidence and severity will be scored based on a visual analog scale and the headache score identified on the designated LLQ score at a given altitude
3. Measurement of the optic nerve sheath diameter (ONSD) using bedside ultrasound have been shown to correlate with clinical and radiologic signs/symptoms of increased intracranial pressure

Overall study start date
01/10/2008

Completion date
30/11/2008

Eligibility

Key inclusion criteria
1. Healthy men or women between the ages of 18 and 65 without any current illness
2. Travelling directly to either Mount Everest Base camp or Kala Patthar
3. Not using any drugs for the prevention of altitude sickness or headache

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350

Key exclusion criteria
1. Younger than 18 years old or are 65 years or older
2. Going to Gokyo, Chukung Ri, or Island Peak before going to Kala Patthar or Everest base camp
3. Have altitude sickness, more than one mild symptom on the Lake Louise Questionnaire (LLQ) (see below), or significantly depressed oxygen saturation (less than 75%)
4. If female, either known to be pregnant or cannot exclude the possibility of being pregnant, or

have missed menses by over 7 days
5. A known drug allergy to ibuprofen/motrin, naprosyn/naproxen or aspirin
6. Already stayed the night at an altitude of 4500 metres/14,000 feet within the last 9 days
7. Have taken any of the following in the last 2 days: acetazolamide (Diamox®), steroids (dexamethasone/decadron, prednisone), theophylline or diuretics (Lasix®)
8. Have taken any of the following within the last 8 hours: ibuprofen/motrin, naprosyn /naproxen, aspirin or acetaminophen
9. Any serious intracranial abnormalities such as history of brain tumours or pseudotumour cerebri
10. Have any known severe uncontrolled headache syndrome

Date of first enrolment
01/10/2008

Date of final enrolment
30/11/2008

Locations

Countries of recruitment
Nepal

Study participating centre
Maharjgunj
Kathmandu
Nepal
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Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials and Research Governance
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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