Prophylactic sumatriptan for prevention of Acute Mountain Sickness: a double blind, randomised, placebo controlled, clinical trial

Submission date	Recruitment status	Prospectively registered	
23/11/2006	No longer recruiting	☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
14/12/2006	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
07/01/2008	Injury, Occupational Diseases, Poisoning		

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

Protocol serial number N/A

Study information

Scientific Title

Acronym

Study objectives

Prophylaxis with sumatriptan will slow or stop the progression of acute mountain sickness (AMS) compared to those taking a placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of Neurology Research Center, Imam Hospital, Tehran University of Medical Sciences, Tehran, Iran.

Study design

Single centre, randomised, two-armed, placebo controlled, participants/outcome assessor blind, clinical trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute mountain sickness

Interventions

- 1. Sumatriptan succinate 50 mg plus orally, once at early ascent
- 2. Placebo: similar color, shape, and weight to interventional group

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sumatriptan succinate

Primary outcome(s)

AMS development due to Lake Louise criteria within 24 hours (International Hypoxia Symposium)

Key secondary outcome(s))

- 1. AMS severity (score more than or equal to five) due to Lake Louise protocol after 24 hours (self-report and clinical assessment)
- 2. Altitude headache occurrence and severity

Completion date

30/11/2006

Eligibility

Key inclusion criteria

- 1. Age of 18 to 60 years
- 2. Ascent to a high altitude of 3500 to 3900 metres above sea level from an altitude of at least 1500 metres
- 3. Consenting participant
- 4. May reasonably be expected to complete a 24 hour trial

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

Key exclusion criteria

- 1. Other neuro-vascular disease such as cerebrovascular accident, and hypoxic cerebral damage
- 2. Cardiovascular disease such as ischaemic heart disease, coronary artery disease, significant valvular disease, congestive heart failure, and uncontrolled hypertension with systolic pressure greater than 180 mmHg or diastolic pressure greater than 110 mmHg
- 3. Pregnancy
- 4. Hypersensitivity to either sumatriptan or acetazolamide or their components

Date of first enrolment

01/01/2006

Date of final enrolment

30/11/2006

Locations

Countries of recruitment

Iran

Study participating centre No15, Shabtab Street

Tehran Iran 19389

Sponsor information

Organisation

Imam Neurology Research Center (Iran)

ROR

https://ror.org/01c4pz451

Funder(s)

Funder type

University/education

Funder Name

Imam Neurology Research Center, Tehran University of Medical Sciences (Iran)

Results and Publications

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	01/09/2007		Yes	No