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

Submission date
23/11/2006

Registration date
14/12/2006

Last Edited
07/01/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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19389

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
SAMS

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
102

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)

Sponsor details
Tehran University of Medical Sciences
No. 23, Dameshgh Street
Vali-e Asr Street
Tehran
Iran
14167

Sponsor type
Research organisation

Website
http://iro.tums.ac.ir/

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/09/2007		Yes	No