

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

Submission date

26/02/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

27/03/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/02/2008

Condition category

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

86-01-54-5304

Study information

Scientific Title

Acronym

GPAMS

Study objectives

Prophylaxis with gabapentin 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)

Approval received from the institutional review board of the Neurology Research Centre, Imam Hospital, Tehran University of Medical Sciences (Iran) on the 11th January 2007 (ref: 85-04-54-4708).

Primary study design

Interventional

Study design

Single centre, randomised, parallel group, two-armed, placebo controlled, participants/outcome assessor blinded, clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute mountain sickness

Interventions

Treatment group one: gabapentin 600 mg orally; single dose within first two hours of ascent.
Treatment group two: mono-hydrate lactose (same shape and weight to gabapentin capsules); single dose within first two hours of ascent.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gabapentin

Primary outcome(s)

1. AMS incidence (Lake Louise acute mountain sickness score of equal or more than three with headache and at least one other symptom)
2. AMS severity (score of five or more)

Key secondary outcome(s)

1. Duration of high-altitude headache free phase after prophylaxis initiation
2. Duration of moderate to severe high-altitude headache free phase after prophylaxis

Completion date

15/03/2007

Eligibility

Key inclusion criteria

1. Age of 15 to 65 years
2. Ascent to a high altitude of 3500 to 3900 metres above sea level from an altitude of at least 1500 metres using cable cars (within 45 to 90 minutes)
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

Sex

Not Specified

Key exclusion criteria

1. Severe cardiac, pulmonary, or liver disease
2. Severely impaired kidney function
3. Current history of alcohol or drug abuse
4. Pregnancy
4. Known allergy to gabapentin
5. Treatment with anticonvulsants or tricyclic antidepressants

Date of first enrolment

15/02/2007

Date of final enrolment

15/03/2007

Locations

Countries of recruitment

Iran

Study participating centre

No. 15, Shabtab Street

Tehran

Iran

19389

Sponsor information

Organisation

Tehran University of Medical Sciences (Iran)

ROR

<https://ror.org/01c4pz451>

Funder(s)

Funder type

Industry

Funder Name

Tehran University of Medical Sciences (Iran)

Funder Name

Darou Darman Pars Pharmaceuticals (DDP) (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	01/03/2008		Yes	No