ISRCTN26123577 https://doi.org/10.1186/ISRCTN26123577

# 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

**Registration date**
27/03/2007

**Overall study status**
Completed

**Last Edited**
18/02/2008

**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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## 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 Januray 2007 (ref: 85-04-54-4708).

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

## Primary study design
Interventional

## 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 |