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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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)

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

Overall study start date
15/02/2007

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

Age group
Adult

Sex
Not Specified

Target number of participants
204

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)

Sponsor details
c/o Professor Ghaffarpour
Neurology Research Centre
Imam Hospital
Faculty of Medicine
Keshavarz Blvd
Tehran
Iran
19389

Sponsor type
University/education

Website
http://www.tums.ac.ir/index.html

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

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	01/03/2008		Yes	No