Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Biomarkers and Acute Mountain Sickness after Active and Passive Ascents to High Altitude in Healthy Men

Protocol summary

Study aim

Determining the levels of some biomarkers at low and high altitudes and their role in the incidence of Acute Mountain Sickness after active and passive ascents

Design

Fifteen subjects are divided into two groups of 7 and 8 people by simple randomization using whithin-subjects design and Counterbalanced order.

Settings and conduct

The subjects will start their ascent from the height of 1900 meters of Tehran Toichal at 8:00 AM. The subjects of mountaineering conditions arrive at the Toichal hotel at about 3:00 P.M. The subjects of the cable car conditions arrive at the hotel at about 3:00 P.M, at the same time as the mountaineering conditions, with a convenient stop at different stations.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy men 20 to 29 years old Lived for at least 6 months in Tehran Body mass index 18.5 to 24.9 (kg / m2) At least two weeks have passed since the second dose of Corona vaccine was given؛ exclusion criteria: Having any acute or chronic illness Having psychological or skeletal disorders Smoking Climbing to altitudes of more than 2500 meters in the two months before the start of the research Blood donation in the two months before the start of the research Flight by aircraft in the two months prior to the start of the research History of high-altitude sports such as mountaineering, skiing and air sports

Intervention groups

The two study groups, climb to an altitude of 3550 meters in two conditions of active (mountaineering) and passive (cable car). After the implementation of the first program, in the second program, the two categories are replaced.

Main outcome variables

Factors such as Cortisol, Heat Shock Protein, Endothelin-1, Interleukin-6, Tumour Necrosis Factor alpha, Arterial Oxygen Saturation changes, and Anxiety are studied to evaluate, predict, and prevent the symptoms of Acute Mountain Sickness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211223053495N1**
Registration date: **2022-06-10, 1401/03/20**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-10, 1401/03/20**
Update count: **0**

Registration date

2022-06-10, 1401/03/20

Registrant information

Name
Sahba Ariandoost

Name of organization / entity
Razi University

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Biomarkers and Acute Mountain Sickness after Active and Passive Ascents to High Altitude in Healthy Men

Public title

Biomarkers and Acute Mountain Sickness after Active and Passive Ascents to High Altitude

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy men 20 to 29 years Lived for at least 6 months in Tehran Body mass index 18.5 to 24.9 (kg.m2) At least two weeks have passed since the second dose of Corona vaccine was given

Exclusion criteria:

Having any acute or chronic illness Suffering from psychological or skeletal disorders smoking Climbing to altitudes of more than 2500 meters in the two months before the start of the research Blood donation in the two months before the start of the research Flight by aircraft in the two months prior to the start of the research History of high-altitude sports such as mountaineering, skiing and air sports

Age

From **20 years** old to **29 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **6**

Blood sampling to measure serum levels of dependent variables (endothelin-1, cortisol, interleukin-6, heat shock protein) and acute mountain sickness and anxiety questionnaire

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: Allocation of subjects will be performed using permuted block randomization with two blocks of eight (one block for the mountaineering and one block for the cable car group). To do this, random allocation software will be used, and someone other than the researchers involved in performing the interventions and measurements will perform it. The random allocation software is a free software that can support block randomization (Version 1.0, May 2004; downloadable at https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html). Each participant will be given a unique code (e.g. 01, 02, 03 ...) and software will randomly generate two different groups as a printable document file.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Razi University

Street address

Razi University, University Ave, Taq-e Bostan,

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.RAZI.REC.1400.076

Health conditions studied

1

Description of health condition studied

Acute Mountain Sickness

ICD-10 code

T70.29

ICD-10 code description

Other effects of high altitude

Primary outcomes

1

Description

Acute Mountain Sickness

Timepoint

About 2 and 6 hours after arrival at the hotel at high altitude as well as the next morning

Method of measurement

Lake Louise Score

2

Description

Changes in serum interleukin 6 levels

Timepoint

4 p.m, day before the ascent, 4 p.m, day of the ascent (one hour after arriving at the hotel at high altitude), 4

p.m, the next day (before returning to low altitude)

Method of measurement

Blood sampling

3

Description

Changes in serum endothelin 1 levels

Timepoint

4 p.m, day before the ascent, 4 p.m, day of the ascent (one hour after arriving at the hotel at high altitude), 4 p.m, the next day (before returning to low altitude)

Method of measurement

Blood sampling

4

Description

Changes in serum Tumor Necrosis Factor-α levels

Timepoint

4 p.m, day before the ascent, 4 p.m, day of the ascent (one hour after arriving at the hotel at high altitude), 4 p.m, the next day (before returning to low altitude)

Method of measurement

Blood sampling

5

Description

Changes in serum Heat Shock Protein levels

Timepoint

4 p.m, day before the ascent, 4 p.m, day of the ascent (one hour after arriving at the hotel at high altitude), 4 p.m, the next day (before returning to low altitude)

Method of measurement

Blood sampling

6

Description

Changes in serum Cortisol levels

Timepoint

4 p.m, day before the ascent, 4 p.m, day of the ascent (one hour after arriving at the hotel at high altitude), 4 p.m, the next day (before returning to low altitude)

Method of measurement

Blood sampling

7

Description

Changes in arterial blood oxygen saturation levels

Timepoint

4 p.m, the day before the ascent, at the first station of the cable car before the ascent, as well as at stations two and five, at the hotel at high altitude after a 10-minute rest, one hour after arriving at the hotel, at 4 p.m the next day (before returning to low height).

Method of measurement

By pulse oximeter device

8

Description

Resting heart rate changes

Timepoint

4 p.m, the day before the ascent, at the first station of the cable car before the ascent, as well as at stations two and five, at the hotel at high altitude after a 10-minute rest, one hour after arriving at the hotel, at 4 p.m the next day (before returning to low height).

Method of measurement

Pulse meter

9

Description

Resting blood pressure changes

Timepoint

4 p.m, day before the ascent, 4 p.m, day of the ascent (one hour after arriving at the hotel at high altitude), 4 p.m, the next day (before returning to low altitude)

Method of measurement

sphygomanometer

10

Description

Anxiety levels

Timepoint

The day before the ascent at 4:00 p.m, the day of the ascent about 2 and 6 hours after entering the hotel at high altitude and also the next morning before returning to low altitude.

Method of measurement

Anxiety Disorders Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: On the day of the ascent, the mountaineers will start their ascent from an altitude of 1900 meters from the first station of the Tochal cable car at 8:00 AM. The subjects of mountaineering conditions travel the distance between stations one and two in about 1 hour, and from station two to station five about 2 hours, and from station five to the Tochal hotel about 3 hours, including 1 hour rest between the way and lunch. They arrive at the hotel at about 3:00 p.m. Subjects will return to the low altitude by cable car at 4:00 p.m on the second day of altitude.

Category

Prevention

2

Description

Intervention group 2: On the day of ascent of the cable

car subjects, at 8 o'clock in the morning from the first station of the Tochal cable car, they start their ascent from a height of 1900 meters with the cable car. Moving from station two: 10:15 am, Moving from the station Five: 2:30 p.m and arrival at the Tochal hotel is 3:00 p.m. The subjects of the cable car conditions will not have any sports or mountaineering activities and will only be sitting or walking slowly at the stations. Subjects will return to the low altitude by cable car at 4:00 p.m on the second day of altitude. After the implementation of the first program, in the second program, the two groups are replaced. An interval of at least two months between the two programs is considered to eliminate the effect of the compatibility of the first program.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran
Full name of responsible person
Sahba Ariandoost
Street address
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Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razi University
Full name of responsible person
Alireza Zebarjadi
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Razi University, Taq-e Bostan, Kermanshah, Iran
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Email
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Web page address
https://sae.razi.ac.ir/~zebarjadiali
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Razi University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Razi University
Full name of responsible person
Sahba Ariandoost
Position
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Latest degree
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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sahbaemailbox@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available