

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Evaluation of the effects of thyme and lavender for treatment and control of high altitude mountain sickness in climbers

Protocol summary

Study aim

Evaluation the effect of Thyme and Lavandula angustifolia for Treatment and Control of high Altitude Disease

Design

randomized controlled clinical trial

Settings and conduct

This study is a randomized clinical trial on climbers in Tehran and Karaj diagnosed with altitude sickness in 2020-2021. thirty climbers will be included in the study based on inclusion and exclusion criteria .Inclusion criteria includes: age between 18 -30, residency at the high altitude of 3000m -3500m for 48 hours and altitude sickness diagnosis.

Participants/Inclusion and exclusion criteria

Some climbers of Tehran and Karaj which are suffering from altitude disease

Intervention groups

Some climbers of Tehran and Karaj which are suffering from altitude disease in Intervention group herbal syrups are going to be prescribed as following: Lavandula angustifolia at the dose of 10000 mg twice a day is going to be prescribed within the 48 hours (produced by Alis company). So as to prescribe Thymus, Thymus vulgaris is going to be prescribed at the dose of 10 mL three times a day within the 48 hours (produced by Kimiagar company). both herbal drugs are going to be prescribed based on drug manufacturer instruction. in control group patients received Acetazolamide at the dose of 500 mg twice a day.

Main outcome variables

Vital signs; heart rate; respiratory rate; blood pressure; axillary temperature; arterial oxygen saturation

General information

Reason for update

Acronym

AMS

IRCT registration information

IRCT registration number: **IRCT20201009048971N1**

Registration date: **2020-12-27, 1399/10/07**

Registration timing: **retrospective**

Last update: **2020-12-27, 1399/10/07**

Update count: **0**

Registration date

2020-12-27, 1399/10/07

Registrant information

Name

Alireza Nouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 2378

Email address

alirezanouri.health@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-05, 1399/08/15

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of thyme and lavender angustifolia for treatment and control of high altitude mountain sickness in climbers

Public title

Thyme and lavandula angustifoliam in treatment of acute mountain sickness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Acute mountain sickness and altitude disease suffering
Camping at the high altitude of 3000m - 3500m from sea level for 48 hours
Age between 18-40 years old
Consent to participate in the study

Exclusion criteria:

Vital sign instability
Heart rate abnormality
High or low blood pressure
High respiratory rate
Decrease of axillary temperature
Decrease of arterial oxygen saturation

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated into the case and control groups using permuted balance block randomization. The blocks are four. Using STATA software, random numbers are generated from 1 to 6. Another number is generated when the previous number is more than 6, without considering it. An individual prepares the random numbers and puts them in pockets with a five-digit serial number. All pockets are opened after including a patient, and the patient is allocated to a group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary IDs**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz Medical University

Street address

N 67 Taeghani North

City

Karaj

Province

Alborz

Postal code

313975546

Approval date

2020-10-14, 1399/07/23

Ethics committee reference number

IR.ABZUMS.REC.1399.181

Health conditions studied**1****Description of health condition studied**

acute mountain sickness

ICD-10 code

T70.2

ICD-10 code description

Other and unspecified effects of high altitude

Primary outcomes**1****Description**

heart rate

Timepoint

each 6 hours within the 48 hours

Method of measurement

pulse oximeter

2**Description**

respiratory rate

Timepoint

each 6 hours within the 48 hours

Method of measurement

counting respiratory rate in a minute

3**Description**

blood pressure

Timepoint

each 6 hours within the 48 hours

Method of measurement

Automatic blood pressure monitors

4**Description**

axillary temperature

Timepoint

each 6 hours within the 48 hours

Method of measurement

Thermometer

5**Description**

arterial oxygen saturation

Timepoint

each 6 hour within the 48 hours

Method of measurement

pulse oximeter

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: prescription of herbal syrups: Lavandula angustifolia at the dose of 10000 mg twice a day is going to be prescribed within the 48 hours (produced by Alis company). So as to prescribe Thymus, Thymus vulgaris is going to be prescribed at the dose of 10 mL three times a day within the 48 hours (produced by Kimiagar company). both herbal drugs are going to be prescribed based on drug manufacturer instruction.

Category

Treatment - Drugs

2**Description**

Control group: Acetazolamide is going to be prescribed at the dose of 500 mg twice a day within 48 hours.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid raises hospital

Full name of responsible person

Dr sahar chobtashani

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Phone

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Dr sahar chobtashani

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No 120, taleghani, Karaj

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

1

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**

Karaj University of Medical Sciences

Full name of responsible person

Dr sahar chobtashani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

No 87 , shahid tahmasebi , taleghani , karaj

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Person responsible for scientific inquiries**Contact**

Name of organization / entity

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Sahar chobtashani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Dr Mahmood bakhtiary

Position

Assistant professor

Latest degree

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Rezabakhtiary@yahoo.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because we didn't finalized our data

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Acute mountain sickness herbal treatment

When the data will become available and for how long

1-14/2/2021

To whom data/document is available

College's

Under which criteria data/document could be used

For control and treatment of ams

From where data/document is obtainable

Dr Mahmood Bakhtiyari

What processes are involved for a request to access data/document

E-mail correspondence to Dr Mahmood Bakhtiyari (mahmood.bakhtiyari@ymail.com) will be responded approximately within a week.

Comments