

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Oxygen Therapy on Patients with Headache Referred to Kashani's Emergency Room for 15 to 60 Minutes

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the effect of oxygen therapy on patients referred to Kashani hospital emergency department for headache for 15 to 60 minutes by visual analog scale (VAS).

Last update: **2021-09-25, 1400/07/03**

Update count: **0**

Registration date

2021-09-25, 1400/07/03

Design

Patients will be divided into two intervention and control groups based on a random number table, sample size 60 (30 people in each group), double-blind.

Registrant information

Name

Mahshid Barzegar Ghahfarokhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3242 4484

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Settings and conduct

This study will be performed in the emergency department of Kashani hospital in Shahrekord.

Participants/Inclusion and exclusion criteria

Age between 18 to 50 years, no mental illness, no brain pathology (brain CT obtained from all patients) or neurological defects in the examination, no high blood pressure, no cancer, no pregnancy or lactation, willingness to cooperate, absence of lung diseases such as asthma, pneumonia, absence of any previous disease being treated.

Recruitment status

Recruitment complete

Funding source

Intervention groups

Control group: in addition to routine treatment, a mask attached to the air container will be located for the patient. Intervention group, in addition to the painkiller, oxygen therapy will be started with a non-rebreather mask. The amount of oxygen consumed will be at least 15 liters. The amount of pain will be measured and recorded using VAS 0, 15, 30, 45, and 60 minutes after the start of treatment by the patient.

Expected recruitment start date

2021-09-16, 1400/06/25

Expected recruitment end date

2021-11-01, 1400/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Headache

Scientific title

Effect of Oxygen Therapy on Patients with Headache Referred to Kashani's Emergency Room for 15 to 60 Minutes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210907052404N1**

Registration date: **2021-09-25, 1400/07/03**

Public title

Effect of Oxygen Therapy on Patients with Headache Referred to Kashani's Emergency Room for 15 to 60

Minutes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 50 years No brain pathologies (brain CT obtained from all patients) or neurological defects on examination No high blood pressure No cancer No pregnancy and lactation Absence of lung diseases such as asthma, pneumonia Absence of any previous disease to be treated.
Exclusion criteria:
Reluctance to cooperate with the study. Patients with pathological lesions

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into 2 groups equally by Permuted Block Randomization method. In each list, separate blocks of 2 will be placed randomly using a random table of numbers. In each list, the order of treatment is determined and therefore, using the double blocks defined based on the random table, patients will be placed in equal numbers in each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both patients and the statistical consultant will not know which group the patients belong to and what type of treatment the other groups will receive.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahre-kord University of Medical Sciences
Street address

Shahrekord, Kashani Blvd., University Headquarters, Building No. 2

City
Shahre-Kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Approval date
2019-07-03, 1398/04/12

Ethics committee reference number
IR.SKUMS.REC.1398.253

Health conditions studied

1

Description of health condition studied

Headache

ICD-10 code

G44.2

ICD-10 code description

Tension-type headache

Primary outcomes

1

Description

Headache rate measured by AVS.

Timepoint

The amount of pain will be measured and recorded by VAS 0, 15, 30, 45 and 60 minutes after the start of treatment by the patient.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, in addition to painkillers, oxygen therapy will be started by Non-rebreather mask, the amount of oxygen consumed will be at least 15 liters. The amount of pain will be measured and recorded by VAS 0, 15, 30, 45 and 60 minutes after the start of treatment by the patient.

Category

Treatment - Devices

2

Description

Control group: Routine headache treatment will be started for all patients. This treatment will be done with Ketorolac 30 mg ampoules. Each patient will be asked to rate their pain with a visual analog scale (VAS). After

recording the pain, the patient's blood pressure will be measured and recorded, and the O2 sat will be recorded before and after treatment. Also, for the control group, in addition to routine treatment, a mask connected to the air conditioner will be given.

Category

Treatment - Devices

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

Emergency department of Kashani Hospital in Shahrekord

Full name of responsible person

Mahshid Barzegar Ghahfarokhi

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Shahrekord, Parstar St., Ayatollah Kashani Hospital

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Deputy of research and technology

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Kashani Blvd., University Headquarters, Building No. 2

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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

Shahre-kord University of Medical Sciences

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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Mahshid Barzegar Ghahfarokhi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Nurse St., Ayatollah Kashani Hospital

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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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

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available