

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of premedication of dexmedetomidine and alfentanil before electroconvulsive therapy on agitation and hemodynamic responses of patients with psychiatric disorders

Protocol summary

Summary

Objectives: Electroconvulsive therapy is an effective treatment for many psychiatric disorders, especially major depression, bipolar disorder, and schizophrenia. However, some patients may suffer from agitation, hyper-dynamic responses including transient hypertension and tachycardia and decreased satisfaction after electroconvulsive therapy. Since the hyper-dynamic responses are developed due to increased levels of epinephrine and norepinephrine in plasma, alpha-2 agonists reduce the sympatho-adrenal responses induced by pain and result in hemodynamic stability and also reduce the need for anesthetics during many surgeries. Dexmedetomidine is an α_2 receptor agonist with neurological and lower cardiovascular effects. Has been reported that the drug is effective in the treatment of agitation after electroconvulsive therapy. Alfentanil is a fast-acting opiate with a short duration of action. In recent studies, the drug had beneficial effects in the treatment of tachycardia and hypertension in at-risk patients without reducing seizure duration. The aim of this study is to compare the effects of these two drugs on agitation, seizure duration, and hemodynamic parameters after electroconvulsive therapy. Design: Block randomization, double blind, with placebo, trial phase 2, including 75 patients who undergo electroconvulsive therapy. Setting and conduct: Thiopental, 3 mg/kg, IV injection to induce anesthesia. Succinylcholine, 0.5 mg/kg, IV injection for muscle relaxation. Participants including major eligibility criteria: All patients who are supposed to undergo electroconvulsive therapy. Intervention: Dexmedetomidine, 0.5 $\mu\text{g}/\text{kg}$ (volume 2 ml with distilled water), IV injection. Alfentanil, 10 $\mu\text{g}/\text{kg}$ (volume 2 ml with distilled water), IV injection. Normal saline, 2 ml, IV injection in control group. Main outcome measures: Agitation score, Patient satisfaction, Seizure duration,

Systolic blood pressure, Diastolic blood pressure, Mean Arterial blood pressure, O2 saturation, Heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014103119769N1**

Registration date: **2015-01-11, 1393/10/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-11, 1393/10/21

Registrant information

Name

Niknam Bagheri

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of premedication of dexmedetomidine and alfentanil before electroconvulsive therapy on agitation and hemodynamic responses of patients with psychiatric disorders

Public title
Comparison of dexmedetomidine and alfentanil before brain shock on patient's agitation

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 1. ASA class I-II 2. Age between 18-50 years old 3. Patients satisfaction 4. Not pregnant 5. No history of cardiovascular diseases (Arrhythmia, ischemia, and heart block) 6. Not taking beta-receptor blockers 7. Not taking opioids Exclusion criteria: 1. Lack of patients cooperation 2. Patients who have tonic-clonic seizures less than 25 seconds. 3. Patients who need more than 60% of energy for tonic-clonic seizure. 4. Severe hemodynamic instability requiring medical treatment. 5. sensitivity to the drugs used in this study.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The patients were assigned alternately to either the dexmedetomidine or alfentanil group. Patients and researchers were not aware of the type of used medication.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences. Basij Square. Sardasht. Arak. Iran

City

Arak

Postal code

Approval date

2014-02-24, 1392/12/05

Ethics committee reference number

92-159-17

Health conditions studied

1

Description of health condition studied

Agitation

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

Agitation score

Timepoint

After intervention and recovery

Method of measurement

Behavior score questionnaire

2

Description

Patient satisfaction

Timepoint

After intervention and recovery

Method of measurement

Satisfaction scale questionnaire

3

Description

Seizure duration

Timepoint

After intervention and from the onset of seizure

Method of measurement

By chronometer and recording in questionnaire

4

Description

Systolic blood pressure

Timepoint

At baseline, 5, and 15 minutes after the intervention and

at the end of study

Method of measurement

By sphygmometer and recording in questionnaire

5**Description**

Diastolic blood pressure

Timepoint

At baseline, 5, and 15 minutes after the intervention and at the end of study

Method of measurement

By sphygmometer and recording in questionnaire

6**Description**

O2 saturation

Timepoint

At baseline, 5, and 15 minutes after the intervention and at the end of study

Method of measurement

By pulse oximeter and recording in questionnaire

7**Description**

Heart rate

Timepoint

At baseline, 5, and 15 minutes after the intervention and at the end of study

Method of measurement

By monitoring and recording in questionnaire

Secondary outcomes

empty

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

Intervention 1. Dexmedetomidine, 0.5 µg/kg (volume 2 ml with distilled water), IV injection.

Category

Treatment - Drugs

2**Description**

Intervention 2. Alfentanil, 10 µg/kg (volume 2 ml with distilled water), IV injection.

Category

Treatment - Drugs

3**Description**

Intervention 3. Normal saline, 2 ml, IV injection in control group.

Category

Treatment - Drugs

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

Amir kabir hospital

Full name of responsible person

Dr Niknam Bagheri

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Amir kabir hospital. Parastar square. Rah-Ahan street. Arak. Iran

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

Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr Ali Asghar Yaghoobi

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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

Arak University of Medical Sciences, Vice Chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty