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 α2 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 µg/kg (volume 2 ml with distilled water), IV injection. Alfentanil, 10 µg/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

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

n.bagheri@arakmu.ac.ir

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

Street address

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

City

Arak

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

Street address

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

City

Arak

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

Arak University of Medical Sciences

Full name of responsible person

Dr Niknam Bagheri

Position

Anesthesiology resident

Other areas of specialty/work

Street address

Arak University of Medical Sciences. Basij Square.

Sardasht. Arak. Iran

City
Arak

Postal code

Phone
+98 86 3417 3641

Fax

Email
n.bagheri@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Niknam Bagheri

Position
Anesthesiology resident

Other areas of specialty/work

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

City
Arak

Postal code

Phone
+98 86 3417 3641

Fax

Email
n.bagheri@arakmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Niknam Bagheri

Position
Anesthesiology resident

Other areas of specialty/work

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

City
Arak

Postal code

Phone
00

Fax

Email
n.bagheri@arakmu.ac.ir

Web page address

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