

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 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  $\alpha_2$  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

##### 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**

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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*