

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparison of effect of Dexmedetomidine and Remifentanil added to Thiopental for hemodynamic responses and seizure time in mood disorder patients who are candidate for ECT

#### Protocol summary

##### Study aim

Aim of this study is evaluation of the effect of Dexmedetomidine and Remifentanil added to Thiopental on hydrodynamic responses and seizure time in mood disorder patients are candidate for ECT .

##### Design

This study is clinical trial and double-blind. 90 patients with mood disorder candidates for ECT will be randomly divided into two groups of Dexmedmotidine and Remifentanil. Groups of study are parallel.

##### Settings and conduct

90 patients with mood disorder candidate ECT referring to Amir Kabir Hospital of Arak are included in this study. The study is double-blind. This study is clinical trial. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome elevator and analyzer don't aware from grouping.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with mood disorder, 18-50 years old Exclusion criteria: having renal, liver, heart and lung diseases ,contraindication for ECT, patients with head injuries, patients who do not seizure after taking electroshock, patients requiring intubation after electroshock due to respiratory impairment and long-term apnea.

##### Intervention groups

Patients will be randomly divided into two equal groups of 45 Dexmedetomidine and Remifentanil. In the Dexmedmotidine group, 0.5 micro gram in kilogram Dexmedetomidine will be injected intravenously and slowly before anesthesia induction. In the Remifentanil group, 100 micro gram in kilogram of Remifentanil is injected intravenously and slowly.

##### Main outcome variables

Blood pressure - heart rate - seizure duration - recovery duration - agitation - patient satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N90**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

##### Registration date

2018-12-29, 1397/10/08

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-09, 1397/01/20

##### Expected recruitment end date

2019-04-09, 1398/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of effect of Dexmedetomidine and Remifentanil added to Thiopental for hemodynamic responses and seizure time in mood disorder patients who are candidate for ECT

### Public title

Comparison of effect of Dexmedetomidine and Remifentanil added to Thiopental for hemodynamic responses and seizure time in mood disorder patients who are candidate for ECT

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All patients with mood disorder candidate electroshock 18-55 years old

#### Exclusion criteria:

having renal, liver, heart and lung diseases patients who have been in addition to psychotic mood disorders contraindication for ECT patients with head injuries patients with head injuries, patients who do not seizure after taking ECT patients requiring intubation after ECT due to respiratory impairment and long-term apnea

### Age

From **18 years** old to **55 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple randomization with random numbers

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Of Arak University Of Medical Sciences

##### Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

Markazi

##### Postal code

848176941

#### Approval date

2018-02-26, 1396/12/07

#### Ethics committee reference number

IR.ARAKMU.REC.1396.298

## Health conditions studied

### 1

#### Description of health condition studied

Mood disorder

#### ICD-10 code

F06.3

#### ICD-10 code description

Mood disorder due to known physiological condition

## Primary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

Before, in the recovery and after the ECT

#### Method of measurement

Barometer

### 2

#### Description

Heart rate

#### Timepoint

Before, in the recovery and after the ECT

#### Method of measurement

Kronometer

### 3

#### Description

Seizure duration

#### Timepoint

Duration ECT

#### Method of measurement

Kronometer

#### 4

**Description**

Duration recovery

**Timepoint**

Duration in recovery

**Method of measurement**

Kronometer

#### 5

**Description**

Agitation

**Timepoint**

Before, in the recovery and after the ECT

**Method of measurement**

Physical examination

#### 6

**Description**

Satisfaction

**Timepoint**

In the recovery and after the ECT

**Method of measurement**

Physical examination

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**

Intervention group: In the Dexmedmotidine group, 0.5 micro gram in kilogram Dexmedetomidine added to Thiopental will be injected intravenously and slowly before anesthesia induction.

**Category**

Treatment - Drugs

#### 2

**Description**

Intervention group: In the Remifentanil group, 100 micro gram in kilogram of Remifentanil added Thiopental is injected intravenously and slowly.

**Category**

Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Amirkabir hospital

**Full name of responsible person**

Dr Hamidreza Jamilian

**Street address**

Amirkabir hospital, Parastar Square

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 86 3222 2003

**Email**

hjamilian@arakmu.ac.ir

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Arjmandzadegan

**Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

848176941

**Phone**

+98 86 3417 3638

**Fax**

+98 86 3417 3638

**Email**

arjmandzadegan@arakmu.ac.ir

**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

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Hamidreza Jamilian  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Amirkabir hospital, Parastar square  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Fax**  
+98 86 3222 2003  
**Email**  
Jamilian@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 Alireza Kamali  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Valiasr Hospital, Valiasr square, Shahid Shirodi street  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 68 3222 2003  
**Fax**  
+98 86 3222 2003  
**Email**  
alikaliiir@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences  
**Full name of responsible person**  
Dr Faezeh Heidarbeigi  
**Position**  
Resident of psychology  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Psychiatrics  
**Street address**  
Payambar Azam Complex, Basij Square, Sardasht, Arak  
**City**  
Arak  
**Province**  
Markazi  
**Postal code**  
3814957558  
**Phone**  
+98 86 3222 2003  
**Fax**  
+98 86 3222 2003  
**Email**  
faezeh.heydarbagi@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

When we publish article in journal

### When the data will become available and for how long

After the article is published

### To whom data/document is available

researcher in university

### Under which criteria data/document could be used

If there are additional questions

### From where data/document is obtainable

Dr Alireza Kamali

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

They have to write letters to the professors and the university

### Comments