

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of premedication Dexmedetomidine and remifentanil and Labetalol before ECT on hemodynamic responses and seizure time in patients

#### Protocol summary

##### Study aim

Aim of this study was comparison of premedication Dexmedetomidine and Remifentanil and Labetalol before ECT on hemodynamic responses and seizure time in patients

##### Design

144 patients candidate electroshock will enter this study. This study is clinical trial and double blind. We will divide patients in 3 groups.

##### Settings and conduct

144 patients candidate electroshock will enter this study. This study is clinical trial and double blind. This study is double blind. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 16-60 years, both of gender, no history of drug use, not pregnancy, no history of cardiovascular disease (arrhythmia, ischemia, heart block), no taking beta-blocker medication, insensitivity to the drugs used in this study, patients with schizophrenia diagnosis  
Exclusion criteria: Lack of consent to cooperate, patients who require more than 60% energy for tonic clonic seizures, patients whose clonic tonic seizures are less than 25 seconds, all patients with ECT undergoing arrhythmia or hemodynamic threatening changes requiring intervention therapies.

##### Intervention groups

We inject 0.5 micro gram in kilogram Dexmedetomidin.  
We inject 0.2 milliliter in kilogram Labetalol. We inject 20 milliliter normal saline.

##### Main outcome variables

blood pressure-heart rate-seizure duration-recovery duration-satisfaction rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N89**

Registration date: **2018-12-16, 1397/09/25**

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

Last update: **2018-12-16, 1397/09/25**

Update count: **0**

##### Registration date

2018-12-16, 1397/09/25

##### 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

2018-08-23, 1397/06/01

##### Expected recruitment end date

2020-08-22, 1399/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of premedication Dexmedetomidine and remifentanyl and Labetalol before ECT on hemodynamic responses and seizure time in patients

### Public title

Comparison of premedication Dexmedetomidine and remifentanyl and Labetalol before ECT on hemodynamic responses and seizure time in patients

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

16-60 years both of gender No history of drug use Not pregnancy No history of cardiovascular disease (arrhythmia, ischemia, heart block) No taking beta-blocker medication Insensitivity to the drugs used in this study Patients with schizophrenia diagnosis

#### Exclusion criteria:

Lack of consent to cooperate Patients who require more than 60% energy for tonic clonic seizures. Patients whose clonic tonic seizures are less than 25 seconds. All patients with ECT undergoing arrhythmia or hemodynamic threatening changes requiring intervention therapies.

### Age

From **16 years** old to **60 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Outcome assessor
- Data analyser

### Sample size

Target sample size: **144**

### 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. Outcome evaluator 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 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

2018-08-19, 1397/05/28

### Ethics committee reference number

IR.ARAKMU.REC.1397.133

## Health conditions studied

## 1

### Description of health condition studied

Psychotic patients

### ICD-10 code

F06.0

### ICD-10 code description

Psychotic disorder with hallucinations due to known physiological condition

## Primary outcomes

## 1

### Description

blood pressure

### Timepoint

Start, 1 and 5 and 10 minute before ECT and every 5 minute after ECT to transfer to hospital section

### Method of measurement

Barometer

## 2

### Description

Heart rate

### Timepoint

Start, 1 and 5 and 10 minute before ECT and every 5 minute after ECT to transfer to hospital section

### Method of measurement

Count

## 3

### Description

Seizure duration

### Timepoint

Duration ECT

### Method of measurement

Minute

#### 4

**Description**

Recovery duration

**Timepoint**

After ECT

**Method of measurement**

Minute

#### 5

**Description**

satisfaction

**Timepoint**

After ECT

**Method of measurement**

Check list

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**

Intervention group: We inject 0/5 micro gram in kilogram  
Dexmedetomidin

**Category**

Treatment - Drugs

#### 2

**Description**

Intervention group: We inject 0/2 milliliter in kilogram  
Labetalol.

**Category**

Treatment - Drugs

#### 3

**Description**

Control group: We inject 20 milliliter normal saline.

**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**

Vice Chancellor For Research, Arak University Of  
Medical Science

**City**

Arak

**Province**

Markazi

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**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 Hesamedin Modir

**Position**

Assistante 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 86 3222 2003

**Email**

modir.he@gmail.com

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

Arak University of Medical Sciences

**Full name of responsible person**

Dr Hesamedin Modir

**Position**

Assistente professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Phone**

+98 86 3222 2003

**Email**

modir.he@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Sina Bahramsari

**Position**

Medicine student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht

**City**

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**Province**

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**Postal code**

3848176941

**Phone**

+98 86 3222 2003

**Email**

s.bahramsari@yahoo.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 Modir

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

They have to write letters to the professors and the university

**Comments**