

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 inter 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 inter 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

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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
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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

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Valiasr Hospital, Valiasr square, Shahid Shirodi street

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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

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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

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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