

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison effect of addition Dexmedetomidine and Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

Protocol summary

Study aim

Aim of this study is comparison effect of addition Dexmedetomidine and Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

Design

Patients with mood disorder candidate ECT referring Amirkabir hospital. This study is clinical trial and double blind. 48 patients is in this study.

Settings and conduct

Patients with mood disorder candidate ECT referring Amirkabir hospital. This study is clinical trial and double blind. 48 patients is in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with cognitive dysfunction receive ECT, 18 to 60 years Exclusion criteria: All patients with anesthesia induced cardiac arrest during ECT, all patients who after ECT due to long-term apnea and respiratory distress need to intubation, all patients who don't have seizures during the ECT process.

Intervention groups

We inject 0/5 micro gram in kilogram Dexmedetomidin before intubation in first group and we inject 2/5 milligram Metoprolol 10 minute before intubation.

Main outcome variables

Mean of blood pressure, Heart rate, degree of restlessness, degree of satisfaction, duration of seizure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N87**

Registration date: **2018-10-31, 1397/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-31, 1397/08/09**

Update count: **0**

Registration date

2018-10-31, 1397/08/09

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-20, 1397/02/30

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of addition Dexmedetomidine and Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

Public title

Comparison effect of addition Dexmedetomidine and

Metoprolol to Tiopental on hydrodynamic responses, agitation and patients satisfaction in electro convulsive therapy for patients with mood disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with cognitive dysfunction receive ECT 18 to 60 years

Exclusion criteria:

All patients with anesthesia induced cardiac arrest during ECT All patients who after ECT due to long-term apnea and respiratory distress need to intubation. All patients who don't have seizures during the ECT process.

Age

From **18 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: **48**

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

2018-05-13, 1397/02/23

Ethics committee reference number

IR.ARAKMU.REC.1397.044

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

Mean of blood pressure

Timepoint

Before and after electro convulsive therapy

Method of measurement

Barometer

2

Description

Heart rate

Timepoint

Before and after electro convulsive therapy

Method of measurement

count

3

Description

Degree of restlessness

Timepoint

After electro convulsive therapy

Method of measurement

Agitation score

4

Description

Degree of satisfaction

Timepoint

After electro convulsive therapy

Method of measurement

satisfaction score

5

Description

Duration of seizure

Timepoint

After electro convulsive therapy

Method of measurement

Minute

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We inject 0/5 micro gram in kilogram Dexmedetomidin before intubation in first group.

Category

Treatment - Drugs

2

Description

Intervention group: We inject 2/5 milligram Metoral 10 minute before intubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Hamidreza Jamilian

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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

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

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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 Alireza Kamali

Position

Assistant 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

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Full name of responsible person

Dr Hamidreza Jamilian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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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 Hamidreza Jamilian

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

They have to write letters to the professors and the university

Comments

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Talat Mohammadi

Position

Resident of psychology

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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