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 squre, Shahid Shirodi street

City
Arak

Province
Markazi

Postal code
3814957558

Phone
+98 68 3222 2003

Fax
+98 86 3222 2003

Email
alikamaliir@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