Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparisson of the effect of pretreatment with Hyoscine,Atropine and placebo on hemodynamic stability,recovery time,and ECT side effect

Protocol summary

Summary

Our target is comparission of hyoscine and atropine effect on patient who treat with ECT.randomized triple blind ,uni centere clinical trial.60 patients according to psychological indication and psychologist confirmation are entered and devided into 3 groups randomically excep who are older than 70 and those have medical contraindication for atropine and hyoscine. patients have tachy cardia,bradycardia,arrythmia,hypotension and hypertension are excluded.first group receive atropine0.5mg/kg as pretreatment,second group hyoscine 0.1 mg/kg and third group water0.01ml/kg .induction is done with nesdonal 2 mg/kg and succinyl choline 0.5mg/kg.blood pressure,heart rate are measured before pretreatment,after and before induction,emmediately and 1,3,5 minutes after shock.duration of convulsion according to seconds,recovery time by minutes and volume of respiratory secretions by times to suction are measured.hearte rate by ECG monitoring,duration of convulsion by EEGand o2 saturation by pulse oximetry.data collection and sampling is done from Farvardin 1393 untill Shahrivar 1393

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100719431N1**
Registration date: **2015-01-12, 1393/10/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-12, 1393/10/22

Registrant information

Name

Ali Khatibi

Name of organization / entity

Iums

Country

Iran (Islamic Republic of)

Phone

+98 21 4495 4217

Email address

khatibi.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran university of medical science

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparisson of the effect of pretreatment with Hyoscine,Atropine and placebo on hemodynamic stability,recovery time,and ECT side effect

Public title

Effect of Hyoscine and Atropine on blood pressure ,heart rate in patient who treated by ECT

Purpose

Treatment

Inclusion/Exclusion criteria

patients according to psychological indication and psychologist confirmation are entered to study patients excep who are older than 70 and those have medical contraindication for atropine and hyoscine. patients have

tachy cardia,bradycardia,arrythmia,hypotension and hypertension are excluded.

Age
To **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Science

Street address
Hemmat High way

City
Tehran

Postal code

Approval date
2014-03-05, 1392/12/14

Ethics committee reference number
922275/105/د

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

2

Description of health condition studied
Persistant delusional disorders

ICD-10 code
F22

ICD-10 code description
Persistant delusional disorder

3

Description of health condition studied
Acute and transient psychotic disorder

ICD-10 code
F23

ICD-10 code description
Acute and transient psychotic disorder

4

Description of health condition studied
Manic disorder

ICD-10 code
F30

ICD-10 code description
Manic episode

5

Description of health condition studied
Bipolar mood diorder

ICD-10 code
F31

ICD-10 code description
Bipolar affective disorder

6

Description of health condition studied
Depressive episode

ICD-10 code
F32

ICD-10 code description
Depressive episode

7

Description of health condition studied
Paranoid personality disorder

ICD-10 code
F60.0

ICD-10 code description
Paranoid personality disorder

Primary outcomes

1

Description
heart rate

Timepoint
after and before pretreatment and after induction and immediately ,after 1,3 and 5 minutes from shock ,heart rate is measured in all patients

Method of measurement
heart rate is measuring by ECG monitoring

2

Description
duration of convulsion
Timepoint
after shock,from the firs movements of patientsto end of convulsion,time is recorded
Method of measurement
duration of convulsion is measured according to seconds

3

Description
time of recovery
Timepoint
from termination of convulsion to allertness of patient is called as recovery time.alertness means the ability of patients to obey orders
Method of measurement
time of recovery,allertness and obey is measuring according minutes

4

Description
volume of respiratory secretions
Timepoint
by convulsion termination ,respiratory secretions may ecceed normal amounts ,so we should suction them
Method of measurement
volume of secretions is measured according to how many times to sucction(1-3 times)1:dry 2:sialorrhea 3:huge amounts of secretions

5

Description
blood pressure
Timepoint
after and before pretreatment and after induction and immediately ,after 1,3 and 5 minutes from shock ,blood pressure is measured in all patients
Method of measurement
blood pressure is measured by cuff around patients arm

Secondary outcomes

1

Description
cognition disorders
Timepoint
cognition disorders are recorded during recovery time
Method of measurement
cognition disorders according to diagnosis confirmation by psychologist

2

Description
other complications
Timepoint
from the patients entrance to end of recovery
Method of measurement
every other complication occurs is recorded by inspection and visualization

3

Description
primary diagnosis
Timepoint
at first after patients entrance, primary diagnosis is recorded in data sheet
Method of measurement
at first primary diagnosis is recorded from medical records

4

Description
age
Timepoint
at first after patients entrance, age is recorded
Method of measurement
age is recorded according to medical records

5

Description
sex
Timepoint
at first,after patients entrance, sex is recorded
Method of measurement
at first sex is recorded from medical records

Intervention groups

1

Description
20 patients accidentally are belong to first group.after initial monitoring and record of information,vital signs include systolic and diastolic blood pressure,pulse rate are recorded in data sheath.in this group all patient recive intravenous atropine 0.5mg (0.01 mg/kg) as pretreatment.induction of anesthesia is done with nesdonal 2mg/kg and succynil choline 0.5 mg/kg. in all patients,blood pressure and pulse rate,time of consciousness ,recovery time, volume of respiratory secretions ,duration of convulsion will be record.
Category
Treatment - Drugs

2

Description
20 patients accidentally are belong to second group.after initial monitoring and record of information,vital signs include systolic and diastolic blood pressure,pulse rate are recorded in data sheath.in this group all patient recive intravenous hyoscine 5-7mg (0.1 mg/kg) as pretreatment.induction of anesthesia is done with nesdonal 2mg/kg and succynil choline 0.5 mg/kg. in all patients,blood pressure and pulse rate ,time of consciousness ,recovery time, volume of respiratory

secretions ,duration of convulsion will be record.

Category

Treatment - Drugs

3

Description

20 patients accidentally are belong to third group.after initial monitoring and record of information,vital signs include systolic and diastolic blood pressure,pulse rate are recorded in data sheath.in this group all patient recive intravenous sterile water 1 ml (0.01 ml/kg) as pretreatment.induction of anesthesia is done with nesdonal 2mg/kg and succynil choline 0.5 mg/kg. in all patients,blood pressure and pulse rate ,time of consciousness ,recovery time, volume of respiratory secretions ,duration of convulsion will be record.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

Behnaz Karimi

Street address

Anesthesiology Department of Hazrat Rasool Akram Hospital, Nyayesh street, Sattar khan, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Miss Maleki

Street address

Hemmat High way.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Behnaz Karimi

Position

Asistant

Other areas of specialty/work

Street address

Anesthesiology Department of Hazrat Rasool Akram Hospital, Niayesh street, Sattarkhan, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 4476 3217

Fax

Email

karimi.behnaz@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Dr Ali Khatibi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Anesthesiology Department of Firoozgar Hospital, Vali asr street, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6650 9059

Fax

+98 21 6650 9059

Email

alikhatibi2002@yahoo.com khatibi

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Behnaz Karimi

Position

Assistant

Other areas of specialty/work

Street address

Anesthesiology Department of Hazrate Rasool Akram Hospital, Niayesh street, Sattar khan, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 4476 3217

Fax

Email

karimi.behnaz@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty