

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 comparisson 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)

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Email address

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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

922275/105/3

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

Persistent delusional disorders

ICD-10 code

F22

ICD-10 code description

Persistent 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 disorder

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 first movements of patient to 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 alertness of patient is called as recovery time. alertness means the ability of patients to obey orders

Method of measurement

time of recovery, alertness and obey is measuring according to minutes

4

Description

volume of respiratory secretions

Timepoint

by convulsion termination, respiratory secretions may exceed normal amounts, so we should suction them

Method of measurement

volume of secretions is measured according to how many times to suction (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 patient's 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 patient's 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 patient's 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 patient's entrance, age is recorded

Method of measurement

age is recorded according to medical records

5

Description

sex

Timepoint

at first, after patient's entrance, sex is recorded

Method of measurement

at first sex is recorded from medical records

Intervention groups

1

Description

20 patients accidentally 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 sheet. In this group all patients receive intravenous atropine 0.5 mg (0.01 mg/kg) as pretreatment. Induction of anesthesia is done with Nesdonal 2 mg/kg and succinyl 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 recorded.

Category

Treatment - Drugs

2

Description

20 patients accidentally 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 sheet. In this group all patients receive intravenous hyoscine 5-7 mg (0.1 mg/kg) as pretreatment. Induction of anesthesia is done with Nesdonal 2 mg/kg and succinyl 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

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Person responsible for scientific inquiries

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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