

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study The effect of supportive_ educational nursing interventions on cognitive status of patients treated with Electroconvulsive Therapy (ECT)

Protocol summary

Summary

Objective: Determining the effects of supportive_ educational nursing interventions on cognitive status of patients treated with ECT at Razi Academic Hospital in Urmia. Inclusion criteria: Patients with 18-60 years old, with no major cognitive and sensory impairments. Exclusion criteria: Patients who receive more than one attempt of electrical shock treatment in one day in order to induce effective convulsive response. Target population: Hospitalized psychiatric patients who have been assigned to ECT treatment by their psychiatrists. Sample size: 102 Patients will be randomly assigned into intervention and control groups (n = 51 in each group). Intervention: The intervention of this study consists of two parts: Patient education and supportive cares. During this period the control group, will receive education routine and usual care made by nurses. The timing of these interventions will begin at recommendation of ECT treatment for patients and will continue and will continue after the 6th session of ECT. Instruments for data gathering and measuring will be demographic information questionnaire and Mini Mental Status Examination. Primary outcome measure: Cognitive Status of patient's in the both control& intervention groups. Within 15, 30, 60 min and 24 hrs after the first, third and sixth ECT sessions will be evaluated.

General information

Acronym

Electroconvulsive Therapy (ECT)

IRCT registration information

IRCT registration number: **IRCT2015052916564N4**

Registration date: **2015-07-21, 1394/04/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-21, 1394/04/30

Registrant information

Name

Molood Radfar

Name of organization / entity

Urmia University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study The effect of supportive_ educational nursing interventions on cognitive status of patients treated with Electroconvulsive Therapy (ECT)

Public title

Cognitive status of patients treated with Electroconvulsive Therapy (ECT)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-60 year; lack of physical disease leads to cognitive impairment; lack of chronic disease and disability; and negative symptoms of schizophrenia, associated with their impaired reality-testing ability. Exclusion criteria: Patients who are receiving less than 6 sessions of ECT; patients who receive more than one attempt of electrical shock treatment in one day in order to induce effective convulsive response.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

Street address

Urmia alley, Resalat Blvd, Urmia

City

Urmia

Postal code

5714783734

Approval date

2015-02-28, 1393/12/09

Ethics committee reference number

ir.umsu.rec.1393.282

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

Major depression

ICD-10 code

F32.3

ICD-10 code description

Severe depressive episode with psychotic symptoms

3

Description of health condition studied

Bipolar mood disorder

ICD-10 code

F31.9

ICD-10 code description

Bipolar affective disorder, unspecified

Primary outcomes

1

Description

Cognitive status

Timepoint

Within the period of 15, 30, 60 minutes and 24 hours after the first, third and sixth Electroconvulsive Therapy

Method of measurement

Mini Mental Status Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention consists of two parts: First part of the intervention consists of patient-education by the researcher who has experience as psychiatric nurse. This part will be done after determining the educational needs of the patient and according to previous information and the level of education. Educative intervention will be 30 minutes sessions which will be face-to-face and individually performed in the psychiatric-exam room located within the psychiatric wards. Material presented in this program; include a brief description on the electro convulsive therapy, introduction to its application, the beneficial effects of treatment, methods and preparations, complications, drugs and nursing care before and after ECT. The second part of intervention will be supportive in nature. It will begin just before the each ECT session and will continue after 2 hours of ECT administration. These interventions include effective communication with the patient and supportive care in three dimensions: Information, emotional and physical,

including providing information to patients, Responding to questions asked by patients before, During and after the sessions, Explaining the reasons for using this method in patients, explaining the responsibilities of treatment group members, encouraging to express feelings, assessing negative beliefs and fears of patients. Stablishing mutual trust, as well as physical care of these patients due to patient safety in terms of damage due to cognitive impairment after ECT, encouraging patient to do physical activity in order to reduce physical pain between sessions.

Category

Other

2

Description

Control group: Control group will receive education routine and usual care by nurses including: NPO, Voiding , Leaving jewelry and metals

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Academic Hospital

Full name of responsible person

Dr. Rahim Khalilzadeh

Street address

km 3 road salmas, Razi Academic Hospital, urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Urmia University of Medical Sciences, Vice chancellor for reasearch

Full name of responsible person

Dr. iraj Mohebbi

Street address

Urmia alley, Resalat Blvd, Urmia

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urmia University of Medical Sciences, Vice chancellor for reasearch

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

Urmia University of Medical Sciences, Nursing and Midwifery Faculty

Full name of responsible person

Sarieh Sheikhmohammadi

Position

The master science student of nursing

Other areas of specialty/work

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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