

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing cyproheptadine and placebo efficacy in prevention of delirium incidence in patients hospitalized in intensive care unit

Protocol summary

Summary

Purpose of the study is comparing cyproheptadine and placebo efficacy in prevention of delirium incidence in critically ill patients. In a double blind randomized clinical trial 40 non-cardiac surgical patients who are admitted to general ICU of Imam Khomeini Hospital will be recruited. Patients with cyproheptadine contraindication will be excluded. Recruited patients simply randomized in the cyproheptadine or placebo group. Patients in cyproheptadine group will be received cyproheptadine tablet 4 mg orally three times daily for 7 days from the day of ICU admission. Patients in control group will receive placebo tablet orally three times daily for 7 days from the day of ICU admission. Cyproheptadine and placebo tablets are same in packaging and the responsible researchers and patients will be blinded. Incidence of delirium will be assessed as daily interval based on the Confusion Assessment Method- Intensive Care Unit (CAM-ICU) questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312203449N13**

Registration date: **2014-01-10, 1392/10/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-10, 1392/10/20

Registrant information

Name

Hossein Khalili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6695 4715

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khalilih@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Grant of Tehran University of Medical Sciences

Expected recruitment start date

2013-10-01, 1392/07/09

Expected recruitment end date

2015-10-01, 1394/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing cyproheptadine and placebo efficacy in prevention of delirium incidence in patients hospitalized in intensive care unit

Public title

Cyproheptadine for prevention of delirium in critically ill patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Non-cardiac surgical patients who are admitted to ICU and are hospitalized in Intensive Care Unit (ICU) for at-least 7 days. Exclusion Criteria: Patients with history of neurological diseases, psychiatric disorders, cyproheptadine hypersensitivity, active GI bleeding, glaucoma, urinary retention and arrhythmia will be excluded from the study.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Ghods Ave.

City

Tehran

Postal code

Approval date

2013-09-01, 1392/06/10

Ethics committee reference number

92-02-33-23168

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F54

ICD-10 code description

Sudden changes in patients' behavioral and psychological conditions

Primary outcomes

1

Description

Incidence of Delirium

Timepoint

At ICU admission and then daily for 7 days

Method of measurement

CAM-ICU Questionnaire

Secondary outcomes

1

Description

Severity of Delirium

Timepoint

At ICU admission and then daily for 7 days

Method of measurement

CAM-ICU Questionnaire

Intervention groups

1

Description

Cyproheptadine Tab (Amin Pharmaceutical Company, Isfahan, IRAN), 4mg TDS orally from admission time, as daily interval for 7 days. Incidence and severity of patients' delirium will be assessed as daily interval based on the CAM-ICU questionnaire.

Category

Prevention

2

Description

Placebo Tab (Amin Pharmaceutical Company, Isfahan, IRAN), 4mg TDS orally from admission time, as daily interval for 7 days. Incidence and severity of patients' delirium will be assessed as daily interval based on the CAM-ICU questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Hossein Khalili

Street address

Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of

Medical Sciences
Full name of responsible person
 Masoud Yunesian
Street address
 Ghods Ave.
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice Chancellor for Research, Tehran University of Medical Sciences
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

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Tehran University of Medical Sciences
Full name of responsible person
 Hossein Khalili
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 Pharm. D
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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