Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 21 6695 4715

Email address

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 assesses 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 assesses 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

Position
Pharm. D

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