

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of Melatonin on agitation and delirium in hospitalized patients with head trauma

Protocol summary

Summary

In this study the effect of Melatonin are measured in 118 patients with head trauma in ICU. Patients aged 18 - 55 years and Glasgow Coma Score (GCS) more than 9 to less or equal to 13 were studied. Patients with history of mental disorders, psychotropic drug abuse, and organic brain disorder are excluded. All patients were divided into two groups, A and B. IN group A took Melatonin 5 mg orally at 9 pm o'clock and group B took 5mg synthetic tablet as placebo. In two groups, if agitation occurs, bolus Midazolam 0.02-0.04 mg / kg PRN (PRN"when necessary") intravenously to achieve Richmond score above 3, for pain control Morphine 0.02-0.04 mg / kg PRN intravenously to achieve a visual analog scale (VAS) less than 3 and if delirium occurred based on Confusion Assessment Method for the ICU (CAM-ICU) Haloperidol 0.02-0.04 mg / kg will be used. Melatonin has been improved control of agitation and delirium

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071016917N2**

Registration date: **2014-07-20, 1393/04/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-20, 1393/04/29

Registrant information

Name

Ali Ashraf

Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-08-01, 1393/05/10

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Melatonin on agitation and delirium in hospitalized patients with head trauma

Public title

Effect of Melatonin on the incidence of agitation and delirium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Age 18-55 years; Glasgow Coma Score (GCS) more than 9 to less or equal to 13 Exclusion criteria: History of mental disorders;Psychotropic drug abuse; Organic brain disorder

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3
Groups that have been masked
No information
Sample size
Target sample size: **118**
Randomization (investigator's opinion)
N/A
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
Guilan University of Medical Sciences
Street address
Namjoo street
City
Rasht
Postal code
4193893345
Approval date
2013-12-07, 1392/09/16
Ethics committee reference number
1920341314

Health conditions studied

1

Description of health condition studied
Head injury
ICD-10 code
G90-G99
ICD-10 code description
Other disorders of the nervous system

Primary outcomes

1

Description
Delirium
Timepoint
Every 12 hours upto 10 days
Method of measurement
CAM-ICU

2

Description
Agitation
Timepoint
Every 12 hours to 10 days
Method of measurement
Richmond score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention1:Melatonin 5mg oral dose every night at 9 pm upto 10 days
Category
Prevention

2

Description
Intervention 2:Synthetic oral placebo tablet
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hospital
Full name of responsible person
Ali Ashraf
Street address
Parastar Street
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Guilan University of Medical Sciences
Full name of responsible person
Abtin Heidarzadeh
Street address
Shahid beheshti Highway
City
Rasht
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 of Guilan 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

Name of organization / entity
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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