Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Assessment of the thiamine effect on post-operative delirium occurrence in patients undergoing hip surgery in intensive care unit

Protocol summary

Study aim

Determining the effect of thiamine on the occurrence of postoperative delirium in patients undergoing hip surgery in the intensive care unit

Design

Patients over 60 years of age and ASA classes I to III who are candidates for hip and proximal femur fracture surgery were randomized into two groups (60 people in the group receiving thiamine (T) and 60 people in the control group receiving placebo (C)) will be divided.

Settings and conduct

Patients over 60 years of age hospitalized in the special care department of Imam Khomeini Hospital in Urmia who underwent hip surgery and had a previous history of any neuropsychological disorder, severe renal failure, severe liver failure, drug or alcohol abuse, diabetic ketoacidosis, and patients with a history of delirium do not have Demographic and clinical information, duration of anesthesia, recovery time, medications taken, under mechanical ventilation, evaluation of acute physiological problems and chronic health grade II at the time of admission, and daily evaluation of organ failure will be recorded consecutively. Patients will be divided into two equal groups.

Participants/Inclusion and exclusion criteria

Patients over 60 years old who are hospitalized in the intensive care unit after hip surgery,Failure to enter: patients with a history of mental disorders Severe renal failure Severe liver failure Drug or alcohol abuse Diabetic ketoacidosis History of delirium

Intervention groups

In the intervention group, a 300 mg vitamin B1 thiamine pill will be taken daily for three days, and in the control group, a placebo will be provided daily for 3 days with the same color and appearance as thiamine from Karen Pharmaceutical Company, Karen Vital Food Supplements.

Main outcome variables

Prevent delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230222057489N1**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

ALIAKBAR VAKILI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

dr.mn.vakili@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the thiamine effect on post-operative delirium occurrence in patients undergoing hip surgery in intensive care unit

Public title

Assessment of the thiamine effect on post-operative delirium occurrence in patients undergoing hip surgery in intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 60 years old after hip surgery Hospitalization in the intensive care unit

Exclusion criteria:

Patients with a history of mental disorder Severe renal failure Severe liver failure Drug or alcohol abuse Diabetic ketoacidosis History of delirium

Age

From **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **55**

More than 1 sample in each individual

Number of samples in each individual: **1**

One group will receive a 300 mg oral thiamine tablet daily and the other group will receive a placebo for 3 days based on the block randomization method. A placebo with the same color and appearance as thiamine will be prepared and assigned by the pharmaceutical department.

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by the random permutation block design method of two treatments with 5 blocks. First, 5 blocks of the composition (ABABA) will be listed and a code will be assigned to each, then according to the sample size equal to 55, 11 blocks will be selected in this order that the letter A for the group Thiamine and letter B will be considered for the control group receiving placebo. Patients will be randomly assigned to two groups A and B using Random Allocation computer software. By selecting the simple randomization method in the randomization method section and entering the total sample size determined in this software, numbers will be given to the patients and the patients will be entered into two groups based on the numbers given by the computer. Randomization will be done based on the permuted block randomization method. Each block will have 5 capacities. Based on the example of ABABA, in each block, people are evenly assigned to two groups. 11 blocks will be built. After that, in each block, people are randomly assigned to the thiamine group (55 people) or the placebo control group (B) (55 people). In this study, randomization will be simple, in a box the numbers 1 to 55 will be written on sheets of paper and placed inside the box in an unspecified manner. One sheet will be removed for each disease, if the number is even. It will be placed in the first group, and if it is an odd number, it will be in the second group.

Blinding (investigator's opinion)

Double blinded

Blinding description

All the codes are secret and the examiner will be a doctor outside the research team responsible for delirium evaluation and they will not be informed about the grouping of people. Both the patients are unaware of the delirium group they are in, and the doctor responsible for delirium assessment will not know the patient group. A placebo with the same color and appearance as thiamine will be prepared and assigned by the pharmaceutical department. Finally, after collecting the data of each group separately, they will be compared by the evaluator doctor who does not know about the patient group. The primary outcome of the study will be the incidence of delirium after surgery.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Emam khomini university hospital-Eeshad AVE-Modarres Blvd-urmia-iran

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Approval date

2022-08-29, 1401/06/07

Ethics committee reference number

IR.UMSU.HIMAM.REC.1401.042

Health conditions studied

1

Description of health condition studied

delirium

ICD-10 code

F05

ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
The effects of thiamine to prevent delirium
Timepoint
76 / 5,000Translation resultsTranslation resultHip surgery patients over the age of 60 were hospitalized in the intensive care unit for 3 days
Method of measurement
First, changes in the level of consciousness in the intensive care unit will be evaluated based on the Richmond restlessness-calmness scale. The degree of restlessness will be divided from 0 to 4. In unconscious patients, the level of sedation will be scored based on the duration of eye contact (-1 to -3). Patients without opening their eyes following verbal stimulation (recorded as -4 to -5) will not be included in the study (45). CAM-ICU includes four characteristics: (1) change in mental status from the beginning, (2) inattention, (3) disturbed thinking, and (4) change in level of consciousness. If the patient is positive for both features 1 and 2 and any feature 3 or 4, delirium will be diagnosed. During the study period, sedation and delirium will be evaluated for each patient every 12 hours. Fentanyl narcotic will be used for patients for post-operative analgesia. If any of the patients develop delirium, haloperidol 5 mg intramuscularly will be used. Any new episode, flushing, itching, diaphoresis, nausea, and phonic edema during the study period will be considered as side effects of thiamine drugs.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention of a 300 mg oral thiamine tablet daily for 3 days
Category
Treatment - Drugs

2

Description
Control group: One 300 mg placebo tablet for 3 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
دانشگاه علوم پزشکی ارومیه بیمارستان امام خمینی
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
sabergholizadeh
Street address
Urmia University of Medical Sciences, is a medical school in Urmia, West Azarbaijan, Iran. Urmia University of Medical College
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Web page address
http://faculty.umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Mohammad Amin Valizad Hasanlui

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available