Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Evaluating the preventive effect of vitamin B1 on Delirium in critically ill patients

Protocol summary

Study aim
Comparison of The effect of Thiamine in Preventing delirium in Post_Gastrointestinal Patients admitted to The Intensive Care Unite

Design
This is a Randomized Double_Blinded clinical Trial .Ninety adults patients undergoing Gastrointestinal surgery admitted to the ICU .They will equally divided into intervention or control group according Permuted Block randomization Method

Settings and conduct
Patients after Gastrointestinal surgery admitted to the ICU of Imam Khomeini Hospital will be evaluated for entry into the study .Ninety patients will equally be assigned to intervention or control group according the Permuted Block Randomization Method .This study is a Double_Blinded trial. Regarding the study of the preventive effect Thiamine patients should not be delirious in the first 24 hours .During the intervention 200mg Thiamine(IV)and Placebo will be prescribed daily .Preparation is done by the nurse in the treatment of room .The researcher and doctor are not aware of the content of the syringes and the type of cods Delirium will be evaluated every 8 hours based on the tool CAM_ICU

Participants/Inclusion and exclusion criteria
Patients with Gastrointestinal surgery older than 18 years old who admitted in ICU will be included in this study and exclusion criteria are Patients with Metabolic disorder epilepsy Severe Hepatic and liver failure pregnant women

Intervention groups
In this group 200 mg injected Thiamine will be administrated for three days and in the control group ,Placebo is injected within three days

Main outcome variables
Prevention of Delirium in patients after Gastrointestinal surgery with a drug (Thiamine) with minimal side effects Evaluation of Hospitalization Time Evaluation of cognitive impairment of patients during the Hospitalization

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190224042815N1**
Registration date: **2019-07-24, 1398/05/02**
Registration timing: **prospective**

Last update: **2019-07-24, 1398/05/02**
Update count: **0**

Registration date
2019-07-24, 1398/05/02

Registrant information
Name
Niayesh Mohebbi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2640-05-18, 2019/02/28
Expected recruitment end date
2640-09-21, 2019/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluating the preventive effect of vitamin B1 on Delirium in critically ill patients

Public title
Evaluating the effect of thiamine on delirium
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with age more than 18 years-old Patients undergoing gastrointestinal surgery Patients admitted to the intensive care unit after gastrointestinal surgery Patients who have proper alertness to enter to the study Patient satisfaction at the time of entering the study
Exclusion criteria:
Patients with age less than 18 year-old Patients with chronic alcohol consumption Pregnancy Patients with severe electrolyte and metabolic disorders Patients with severe liver failure Patients with central nervous system problems
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization unit: Block randomization Randomization tool: SAS statistical software, sealed envelope How to create a random sequence: SAS statistical software
Blinding (investigator's opinion)
Double blinded
Blinding description
Use non-transparent sealed envelopes with random sequences
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University Of Medical Scienses
Street address
Tehran University of Medical Sciences,Ghods Ave. Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
-
Approval date
2640-05-09, 2019/02/19
Ethics committee reference number
IR.TUMS.TIPS.REC.1397.141

Health conditions studied

1

Description of health condition studied
Post operation
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Prevention of Delirium after Gastrointestinal Surgery
Timepoint
Days 2-4
Method of measurement
Evaluation of delirium incidence based on Confusion Assessment method for the Intensive Care Unite (CAM_ICU)

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention Group" : 'The group receiving thiamine hydrochloride 50 mg/ml ampule Ratiopharm GmbH company is injected at a daily dose of 200 mg (4 ampulla) in serum for three days.
Category
Treatment - Drugs

2

Description
"Control group": The group receiving placebo (four CC of normal saline) is injected in the same syringe as the intervention group in the serum for three days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital Complex
Full name of responsible person
Niayesh Mohebbi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods Ave., Tehran, Iran
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msahrai@sina.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Niayesh Mohebbi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript
When the data will become available and for how long
One year after end of the study, data will be published and will be available in databases.
To whom data/document is available
After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes.
Under which criteria data/document could be used
Other researchers are permitted to included the results in their systematic reviews and meta-analysis.
From where data/document is obtainable
Contact scientific responsible person for the clinical trial as needed
What processes are involved for a request to access data/document
After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks.
Comments
Data sharing is according to permission from the sponsor.