

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

Country

Iran (Islamic Republic of)

Phone

+98 21 8841 3590

Email address

niayesh_mohebbi@yahoo.com

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 Sciences

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

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2756

Email

niayesh_mohebbi@yahoo.com

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

City

Tehran

Province

Tehran

Postal code

02166706141

Phone

+98 21 8898 7381

Email

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

Pharmacotherapy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6658 1598

Fax

Email

Niayeshmohebbi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Associate professor

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1419733141

Phone

+98 21 6658 1598

Email

Niayeshmohebibi@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

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Niayesh Mohebibi

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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.