Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Effect of Rivastigmine in postoperative delirium after the Radical surgery

Protocol summary

Study aim
The effect of rivastigmine on postoperative delirium

Design
Eligible patients will be randomly divided into control and rivastigmine groups. Rivastigmine is started in the evening of the day before surgery and will continue in the pre- and postoperative periods until the evening of the sixth day after surgery. Radical surgery will be performed using standard protocol and standard anesthesia.After hydration of the patient, the appropriate size of the spiral endotracheal tube is selected for the patient. Initially, preoxygenation will be performed on the patient for 3 minutes. To induce anesthesia, a standard protocol including fentanyl at a dose of 1 to 2 micrograms per kilogram of body weight, midazolam at a dose of 3 hundred milligrams per kilogram of body weight, and lidocaine at a dose of 1 to 1.5 milligrams per kilogram of body weight will be used.

Settings and conduct
All patients over 60 years of age who are candidates for radical surgery who have referred to Shahid Modarres Hospital will be included in the study completely randomly based on the numbers in the random table of 60 of them.

Participants/Inclusion and exclusion criteria
All patients underwent radical surgery Age over 60 years

Intervention groups
Rivastigmine is given to the patient three times a day in doses of 1.5 mg (4.5 mg per day) as an infusion before, during and after surgery and every 8 hours. The placebo given to the control group will be similar in color to rivastigmine.

Main outcome variables
Bleeding rate; Postoperative delirium; Duration of stay in the ICU; Length of hospital stay; Duration of postoperative consciousness; Postoperative nausea and vomiting; Postoperative dizziness; Train-of-four Fade evaluation; Extrusion time; The amount of drugs used; Electrolyte disturbance; hemoglobin

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201211049679N1**
Registration date: **2021-09-22, 1400/06/31**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-22, 1400/06/31**
Update count: **0**

Registration date
2021-09-22, 1400/06/31

Registrant information
Name
kia kazemzadeh hanani
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8807 6453
Email address
kiiiiia_kzm@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-11, 1400/06/20
Expected recruitment end date
2022-03-11, 1400/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Rivastigmine in postoperative delirium after the

Radical surgery

Public title
Effect of Rivastigmine in postoperative delirium after the Radical surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients underwent radical surgery Age over 60 years
Exclusion criteria:
History of psychiatric disorders Patients in need of emergency surgery Patients with a Mini-Mental State Examination Score (MMSE) of less than 15 Current treatment with cholinesterase inhibitors Using psychiatric drugs Using haloperidol Contraindication for the use of rivastigmine
Age
To **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be entered into the study completely randomly based on random table numbers. Randomization will be done by someone other than the researchers of this project. First, each patient as a member of the community was given a three-digit code (001, 002, 003, ...). Then go to the table, select the starting point and move in the direction of the row or column based on the adjacent three-digit numbers. Select the first three-digit number smaller than the total number of patients as the first sample and ignore numbers greater than the total number of patients. We will continue to do this until we can select 60 items as a sample.
Blinding (investigator's opinion)
Double blinded
Blinding description
We do not inform the participant and researcher about the details of the drugs used (placebo and Rivastigmine). In this study, the doctor who gives the drug to the patient and only with the codes assigned to the drugs (placebo and Rivastigmine), they use them for each patient who will enter the plan and he himself is unaware of how the codes are assigned and the patient himself is the type of drugs (placebo and Rivastigmine). Consumption will be uninformed and only the project instructor will be aware of the drugs (placebo and Rivastigmine) given to patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yemen St ,Shahid Chamran Highway
City
tehran
Province
Tehran
Postal code
1985717443
Approval date
2020-04-21, 1399/02/02
Ethics committee reference number
IR.SBMU.MSP.REC.1399.007

Health conditions studied

1

Description of health condition studied
Patients undergoing radical surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Bleeding rate
Timepoint
before and after intervention
Method of measurement
The amount of bleeding during the operation

2

Description
Postoperative delirium
Timepoint
before and after intervention
Method of measurement
Patient delirium one hour after surgery and at the time of discharge from the intensive care unit.

3

Description

Duration of stay in the ICU

Timepoint

before and after intervention

Method of measurement

Number of days the patient stays in the intensive care unit after surgery.

4

Description

Length of hospital stay

Timepoint

before and after intervention

Method of measurement

Number of days the patient stays in the hospital after surgery.

5

Description

Duration of postoperative consciousness

Timepoint

before and after intervention

Method of measurement

The number of hours the patient regains consciousness after surgery.

6

Description

Postoperative nausea and vomiting

Timepoint

before and after intervention

Method of measurement

The number of times a patient vomits after surgery until discharge from the intensive care unit.

7

Description

Postoperative dizziness

Timepoint

before and after intervention

Method of measurement

Duration of postoperative sensory disturbances and confusion.

8

Description

Train-of-four Fade evaluation

Timepoint

before and after intervention

Method of measurement

Evaluation of peripheral nerve excitability to evaluate neuromuscular block.

9

Description

Extubation time

Timepoint

before and after intervention

Method of measurement

Duration of extubation of the patient after administration of neuromuscular blocking agent.

10

Description

The amount of opiate used

Timepoint

before and after intervention

Method of measurement

The amount of opiate used after surgery.

Secondary outcomes

1

Description

Electrolyte disturbance

Timepoint

before and after intervention

Method of measurement

Having an electrolyte disorder such as hyponatremia.

2

Description

hemoglobin

Timepoint

before and after intervention

Method of measurement

Serum hemoglobin concentration

Intervention groups

1

Description

Rivastigmine (manufactured by Galenus Pharmaceutical Company) will be given to the patient three times a day in doses of 1.5 mg (4.5 mg per day) in the form of infusion before, during and after surgery and every 8 hours. Rivastigmine and placebo (prepared by Abu Reihan Pharmaceutical Company) will be administered through nasogastric tube until the patient is extubated. The given placebo will be similar in color to rivastigmine. The selective dose of rivastigmine was based on previous studies, including the study of Gamberini et al. (20). Rivastigmine is started in the evening of the day before surgery and will continue in the pre- and postoperative periods until the evening of the sixth day after surgery. Radical surgery will be performed using standard protocol and standard anesthesia. . Patients are placed in the supine position and angiocatheter 18 is implanted. After hydration of the patient, the appropriate size of the spiral endotracheal tube is selected for the patient. Initially, preoxygenation will be performed on the patient for 3 minutes. To induce anesthesia, a standard protocol including fentanyl at a dose of 1 to 2 micrograms per kilogram of body weight, midazolam at a dose of 3 hundred milligrams per kilogram of body weight, and lidocaine at a dose of 1 to 1.5 milligrams per kilogram of

body weight will be used. Patients under general anesthesia with propofol 1-2 mg / kg body weight. They will also receive inhalation using isoflurane during surgery. Postoperative analgesics will include morphine and paracetamol. Also, very low doses of meperidine will be used to relieve tremors after surgery. Doses of sedatives as well as analgesics will be reported daily.

Category

Treatment - Drugs

2

Description

The given placebo will be similar in color to rivastigmine. Placebo will also be provided by Abu Reihan Pharmaceutical Company. Which will be randomly assigned to the study group as a control, the researcher will not know which type (drug or placebo) to give to the patient. The placebo is started in the evening of the day before the operation and will continue in the pre- and postoperative periods until the evening of the sixth day after the operation. The exact conditions will be the same as the administration of rivastigmine. Radical surgery will be performed using standard protocol and standard anesthesia. . Patients are placed in the supine position and angiocatheter 18 is implanted. After hydration of the patient, the appropriate size of the spiral endotracheal tube is selected for the patient. Initially, preoxygenation will be performed on the patient for 3 minutes. To induce anesthesia, a standard protocol including fentanyl at a dose of 1 to 2 micrograms per kilogram of body weight, midazolam at a dose of 3 hundred milligrams per kilogram of body weight, and lidocaine at a dose of 1 to 1.5 milligrams per kilogram of body weight will be used. Patients under general anesthesia with propofol 1-2 mg / kg body weight. They will also receive inhalation using isoflurane during surgery. Postoperative analgesics will include morphine and paracetamol. Also, very low doses of meperidine will be used to relieve tremors after surgery. Doses of sedatives as well as analgesics will be reported daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid modares hospital

Full name of responsible person

kia kazemzadeh hanani

Street address

End of Saadat Abad Street - the intersection of Yadegar Imam and Saadat Abad highways

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kiiiiia_kzm@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

kia kazemzadeh hananai

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Shahid Chamran Highway, Yemen St., next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

kia kazemzadeh hanani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Informed Consent Form
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All collected data will be given in writing in the dissertation and articles.

When the data will become available and for how long
Summer 1401

To whom data/document is available
Everyone

Under which criteria data/document could be used
Everyone

From where data/document is obtainable
Executors and project partners

What processes are involved for a request to access data/document
By referring to Shahid Beheshti University of Medical Sciences, the dissertations section can access all the documents.

Comments