

# 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)

##### Phone

+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

##### City

tehran

##### Province

Tehran

##### Postal code

1998734383

#### Phone

+98 21 2207 4087

#### Email

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

##### Street address

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

##### City

tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 23871

##### Email

kiiiiia\_kzm@yahoo.com

#### 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

##### Street address

Shahid Chamran Highway, Yemen St., next to

Taleghani Hospital, Shahid Beheshti University of  
Medical Sciences

**City**

tehran

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Tehran

**Postal code**

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**Phone**

+98 21 2241 0042

**Email**

kiiiiia\_kzm@yahoo.com

**Person responsible for scientific 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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**Person responsible for updating data**

**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**

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**Email**

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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**