

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of the effect of two general and Regional anesthesia in the incidence of delirium and early post-operative cognitive disorders post in senile patients with hip Fracture.

Protocol summary

Delirium; Early post-operative cognitive disorders

Study aim

The aim of this study is the comparison of the effect of two general and regional anesthesia in the Incidence of delirium and early post-operative cognitive disorders after hip fracture surgery in senile patients.

Design

In a prospective and single blind, phase III clinical trial, ninety-eight senile patients candidated for operative repair of hip fractures, after selection in the study according to inclusion and exclusion criteria and getting informed consent, will be divided randomly (with block randomization method in blocks with 4 participant) into two parallel intervention (general anesthesia) and control (regional anesthesia) groups.

Settings and conduct

The study will be conducted in two university hospital. Before intervention, mental status and cognitive function of the patients as a basic value will be evaluated by MMSE and Wechsler standard tests, then patients of intervention group are going to operation under general anesthesia which is similar for all patients. In the control group, regional anesthesia (spinal or epidural) will be used during the surgery. In the following 5 days cognitive function of the all patients and the incident of the main outcomes would be evaluated with the use of above mentioned tests. The evaluating person in this phase is blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with hip fractures; Age over 50
Exclusion criteria: History of cognitive and mental disorders; Age under 50; consumption of drugs effective on mental and cognitive function

Intervention groups

In the intervention group general anesthesia and in control group regional anesthesia will be used for anesthetic management of the patients during operation.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121107011398N13**

Registration date: **2018-06-26, 1397/04/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-26, 1397/04/05**

Update count: **0**

Registration date

2018-06-26, 1397/04/05

Registrant information

Name

Mohammad Reza Ghodrati

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The comparison of the effect of two general and Regional anesthesia in the incidence of delirium and early post-operative cognitive disorders post in senile patients with hip Fracture.

Public title
The effect of anesthesia technique in the incidence of post-operative delirium and early post-operative cognitive disorders

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients candidate for hip fracture fixation surgery Age over 50 years Have consent for participation in the study ASA physical class I-III
Exclusion criteria:
 Preoperative cognitive disorders Alcohol and opiates abuse ASA physical class over III Not satisfied for participation in the study Any contraindication for selection of general or regional anesthesia History of any surgery and anesthesia in the past month Electrolytic and acid-base drangments History of psychotropic and benzodiazepines usage in the recent past week History of cerebrovascular accident in the past year

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients Respectively, entering the study will be divided by using block randomization (4 person in each block) into two equals 49 cases group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person who is responsible for pre & post operative cognitive tests evaluation is not aware from the grouping of patients. The person who will doing statistical analysis is blind to grouping of the participants.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Siences

Street address

Iran University of Medical Sciences, Shahid Hemmat highway

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Province

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Postal code

1449614535

Approval date

2018-02-21, 1396/12/02

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9511174001

Health conditions studied

1

Description of health condition studied

Postoperative delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

2

Description of health condition studied

Postoperative cognitive disorders

ICD-10 code

F06.7

ICD-10 code description

Mild cognitive disorder

Primary outcomes

1

Description

Incidence of postoperative delirium

Timepoint

The day before and then daily after operation until 5th day

Method of measurement

Mini-mental state examination & Wechsler test

Secondary outcomes

1

Description

Early post operative cognitive disorders
Timepoint
The day before and then daily after operation until 5th day
Method of measurement
MMSE & Weschler tests

Intervention groups

1

Description
Intervention group: General anesthesia
Category
Treatment - Other

2

Description
Control group: Regional anesthesia (spinal & epidural)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
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Sponsors / Funding sources

1

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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
Iran 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After completion of the study and data collection, results will be imported to the main computerized data table. Results including demographic and background information of patients and analytical results will be published through both a thesis and as an article in specialized journals. Public access to the thesis and articles based on it will be assured.

When the data will become available and for how long

All documentation is saved on databases up to 6 years after study's completion. Access to and sharing of the data will be possible.

To whom data/document is available

University administration, editor-in-chiefs of journals, participants, all legally authorized persons.

Under which criteria data/document could be used

Use of study's protocol in further research to assure released data correctness, and to assure correct implementation of the protocol.

From where data/document is obtainable

Person responsible for scientific inquiries & corresponding author via email address: Mohammadreza Ghodrati: mrghodrati@yahoo.com
ghodrati.mr@iums.ac.ir

What processes are involved for a request to access data/document

Study's general data will be communicated by email in shortest delay. Confidential data which will identify patients is only granted if authorized by legal or administrative order

Comments