

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of general anesthesia with etomidate for decrease of signs of bone cement implantation syndrome compare with spinal anesthesia in cemented hip arthroplasty

Protocol summary

Summary

This study is done for prevention and decrease of bone cement implantation syndromes. 160 patients under hip arthroplasty are studies that used cement for their surgery. The patients have a history of sensitivity to etomidate anaphylaxis to cement and patients with A. S. A class IV are excluded from study. this is an interventional study. the patients are divided randomly into two groups containing general anesthesia with etomidate and spinal anesthesia. vital signs are recorded before and after of induction of anesthesia. if this syndrome occurs time and grading and treatment of bone cement syndrome are recorded and comparison in both groups.

General information

Acronym

BCIS or bone cement Syndrome

IRCT registration information

IRCT registration number: **IRCT2012091910882N1**

Registration date: **2012-12-17, 1391/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-17, 1391/09/27

Registrant information

Name

Ali Iravani

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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dairavani@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of general anesthesia with etomidate for decrease of signs of bone cement implantation syndrome compare with spinal anesthesia in cemented hip arthroplasty

Public title

The effect of method of anesthesia in decrease of signs of bone cement implantation syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The patient are candidate for hip arthroplasty; and use cement for their surgery. A. S.A class I-III;HB>10 Exclusion criteria:The pateint be sensitive to etomidate and cement;hip arthroplasty without cement;A. S. A class IV;revesion of hip prothes

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Beheshti Hospital, 5th Kilometer Ravand Bulv

City

Kashan

Postal code

Approval date

2012-10-17, 1391/07/26

Ethics committee reference number

2732/1/5/29/ب

Health conditions studied

1

Description of health condition studied

Bone cement implantation syndrome

ICD-10 code

M96.6

ICD-10 code description

Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate

Primary outcomes

1

Description

blood pressure

Timepoint

induction of anesthesia, before insertion of cement, 5 minute and 10 minute after cement

Method of measurement

barometer(mm hg)

2

Description

puls rate

Timepoint

induction of anesthesia, before insertion of cement, 5 minute and 10 minute after cement

Method of measurement

puls oximetre

3

Description

arterial oxigen saturation

Timepoint

induction of anesthesia, before insertion of cement, 5 minute and 10 minute after cement

Method of measurement

puls oximetre

Secondary outcomes

1

Description

cardiac arrest and death

Timepoint

any time after insertion of cement

Method of measurement

vital signs

Intervention groups

1

Description

Patients under general anesthesia after receiving 500 cc Ringer lactate are inducted with Midazolam (0.3 mg / kg), Fentanyl (2 micg / kg) and Etomidate (0.3 mg / kg). The patients are intubated with Cisatracurium (0.15 mg/kg) and received maintenance dose of etomidate (10 micg / kg/ min).

Category

Prevention

2

Description

Patients undergoing spinal anesthesia after receiving 500 cc Ringer lactate are placed in the sitting or lateral position. Bupivacaine (20 mg) is injected into the subarachnoid space with using a No. 23 spinal needle through the space between the vertebral L3-L4 or L4-L5 or L5 - S1.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Dr Ali Iravani

Street address

Beheshti Hospital, 5th Kilometer Ghotbe Ravandi Bulv

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Kashan University of Medical Sciences, 5 km Road
Ravand

City

kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

kashan Univercity of Medical Sciences

Full name of responsible person

Ali Iravani

Position

Anesthesiologist resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

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Position

Resident of Anesthesia

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty
Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty