Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of Effect of Oral Clonidine Premedication on Blood Loss in Lumbar Spinal Posterior Fusion Surgery with that of Plasebo

Protocol summary

Summary

Objectives: To evaluate the effect of clonidine as a single dose oral preoperative medication on surgical blood loss in posterior spinal fusion surgery and compare it with that of placebo Design: double-blinded randomized clinical trial Setting and conduct: 30 patients candidated for lumbar spine posterior fusion at 3-4 levels, in Rassoul e Akram hospital (Tehran (previous Iran) university of medical sciences); are randomly allocated into 2 groups. The study group (Clonidine group) receive 200micg oral clonidine tablet 60-90 minutes before anesthesia and the control group receive placebo at the same time. Induction and maintenance of anesthesia and the target mean arterial pressure for controlled hypotension with remifentanil are the same in the 2 groups. We compare the amount of blood loss, dose of remifentanil /hour administered, need for nitroglycerine to reach the target mean arterial pressure when remifentanil was not enough, duration of operation and surgeon's satisfaction of a bloodless field between the 2 groups. Participants including major eligibility criteria: 20-65yr old with American Society of Anesthesia (ASA) physical status of I-II candidated for posterior fusion of lumbar spine at 3 to 4 levels due to traumatic vertebral fracture; who don't have any significant underlying disease (hypertension, hepatic or renal disease, coagulation defects, diabetes mellitus), beta-blocker, calcium channel blocker, dioxin, tricyclic antidepressant, anticoagulant or clonidine treatment, drug or alcohol abuse. Intervention: 200 microgram Clonidine tablet administered to the patients in intervention group as a single dose, 60 to 90 minutes before anesthesia Main outcome measures (variables): The amount of blood loss during operation, dose of remifentanil /hour administered, need for nitroglycerine to reach the target mean arterial pressure when remifentanil is not enough, duration of operation and surgeon's satisfaction of a bloodless field

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101205652N1**
Registration date: **2011-03-01, 1389/12/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-03-01, 1389/12/10

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran (previous Iran) University of Medical Sciences

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-06-22, 1389/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Effect of Oral Clonidine Premedication on Blood Loss in Lumbar Spinal Posterior Fusion Surgery with that of Plasebo

Public title
effect of oral clonidine on surgical blood loss
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: 20-65yr old with American Society of Anesthesia (ASA) physical status of I-II candidated for posterior fusion of lumbar spine at 3 to 4 levels due to traumatic vertebral fracture The exclusion criteria: significant underlying disease (hypertension, hepatic or renal disease, coagulation defects, diabetes mellitus), being under beta-blocker, calcium channel blocker, dioxin, tricyclic antidepressant, anticoagulant or clonidine treatment, drug or alcohol abuse.
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran (previous Iran) University of Medical Sciences
Street address
Tehran University of Medical Sciences, Hemmat Highway
City
Tehran
Postal code
Approval date
2009-06-07, 1388/03/17
Ethics committee reference number
4290

Health conditions studied

1

Description of health condition studied
blood loss during posterior spinal fusion surgery
ICD-10 code
S32.0
ICD-10 code description
Fracture of lumbar vertebra

Primary outcomes

1

Description
surgical blood loss
Timepoint
end of operation
Method of measurement
milliliter

Secondary outcomes

1

Description
surgeon's satisfaction of a bloodless field
Timepoint
end of surgery
Method of measurement
surgeon's satisfaction scoring system

2

Description
dose of remifentanil administered per hour to keep mean arterial pressure between 60 - 70 mmHg
Timepoint
end of operation/anesthesia
Method of measurement
milligram/hour

3

Description
need for nitroglycerin added to remifentanil to keep mean arterial pressure between 60 - 70 mmHg
Timepoint
end of surgery
Method of measurement
number of petients who needed TNG in each group

4

Description
occurance of severe/refractive bradycardia (as a complication of clonidine)
Timepoint
when occured during operation/anesthesia

Method of measurement
number of patients

Intervention groups

1

Description
clonidine tablet (oral), 200 microgram, to the study group ,60 - 90 minutes before anesthesia
Category
Treatment - Drugs

2

Description
placebo (pantoprazole tablet), to control group, 60 - 90 minutes before anesthesia
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rassoul-e Akram Hospital (Tehran (previous Iran) University of Medical Sciences, Neurosurgery Operat
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran (previous Iran) University of Medical Science
Full name of responsible person
Doctor Akbar Fotouhi
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Tehran University of Medical Sciences, Between Chamran and Sheykhfalollah Highways, Hemmat Highway, Tehran- Iran
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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
Vice chancellor for research, Tehran (previous Iran) University of Medical Science
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

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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