Evaluation of comparison between Remifentanil infusion and single dose intravenous Hydralazine + Propranolol administration to provide controlled hypotension in patients undergoing Rhino plastic surgery in khalili hospital during 2014-2015

Protocol summary

Summary
Study purpose: evaluation and comparison between Remifentanil infusion and single dose intravenous Hydralazine + Propranolol administration to provide controlled hypotension in patients undergoing Rhino plastic surgery. Method: the sample size in this study is 80 students divided into two groups A and B with 40 members in the age range of 40-20 years. Interventions: group A, besides induction of anesthesia, received 1 mg Inderal and 20 mg Hydralazine. In group B patients are tested under Remifentanil infusion at a rate of 0.1 -0.3 mcg / kg / min. Primary outcome measure: blood pressure decrease and heartbeat rate in two groups A and B.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2015101522173N2
Registration date: 2015-12-09, 1394/09/18
Registration timing: retrospective

Last update: empty
Update count: 0
Registration date
2015-12-09, 1394/09/18

Registrant information
Name
Behshid Javidsharify
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
class II & III ASA; recent (the last 3 months) general anesthesia record; drug abuse; history of allergy to Propranolol or Hydralazine or Remifentanil; high blood pressure; cardiovascular diseases should be eliminated.

Age
From 20 years old to 40 years old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Zand St

City
Shiraz

Postal code

Approval date
2015-09-13, 1394/06/22

Ethics committee reference number
IR.SUMS.REC.1394.115

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10-I15

ICD-10 code description
Hypertensive diseases

Primary outcomes

1

Description
Blood pressure

Timepoint
Before intervention, during intervention, after intervention

Method of measurement
In terms of mmHg, using a Mercury sphygmomanometer

Secondary outcomes

1

Description
Bleeding during surgery

Timepoint
After intervention

Method of measurement
According to surgeon report

Intervention groups

1

Description
In group B patients are tested under Remifentanil infusion at a rate of 0.1 -0.3 mcg / kg / min.

Category
Treatment - Drugs

2

Description
Group A, besides induction of anesthesia , received 1mg Inderal and 20mg Hydralazine.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalili Hospital

Full name of responsible person

Street address

City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Gholamreza Ghazipour

Street address
Shiraz University of Medical Sciences, Zand St.
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
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Position
Anesthesiologist

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Technology

Full name of responsible person
Mahshid Javidsharifi

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PhD student

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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