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

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Recruitment status
Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2015-09-23, 1394/07/01
Expected recruitment end date
2015-11-22, 1394/09/01

Scientific title
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

Public title
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

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criterion: all patients in the range of 20-40 years old with class I ASA. Exclusion criteria: patients in
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

Secondary outcomes

1

Description
- Blood pressure

Timepoint
- Before intervention, during intervention, after intervention

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

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
- Shiraz

Sponsors / Funding sources

1

Sponsor
- Name of organization / entity
  Shiraz University of Medical Sciences

Full name of responsible person
- Dr. Gholamreza Ghazipour

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Person responsible for general inquiries

Contact
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Person responsible for updating data

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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