

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Sep 2026

Comparison of the effect of remifentanyl and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty

Protocol summary

Study aim

Comparison of the effect of remifentanyl and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty

Design

Double-blind randomized clinical trial

Settings and conduct

The drugs are prepared in the operating room by a nurse who is unaware of the type of study with label A in the dexmedetomidine group and label B in the remifentanyl group and are given to a person who is unaware of the specialization of the groups for injection. The person assessing patients and patient satisfaction at the end of the study is also unaware of the allocation of study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-45 y/o, Patients undergoing rhinoplasty surgery
Exclusion criteria: Patients with liver dysfunction, Renal dysfunction, Any known allergy or hypersensitivity to study drugs, analgesics abuse, opium addiction, Diabetes, Hemorrhagic disease, Using anticoagulants, Cerebrovascular disease, Heart block, Cardiovascular disease.

Intervention groups

In the Intervention group one patients will receive 1 µg / kg dexmedetomidine (PFIZER, USA) for 20 minutes and at the same time as induction begins with a dose of 0.6 µg / kg and continues until the end of the operation. In the Intervention group two simultaneously with the induction of anesthesia, in the remifentanyl group (EXIR, IRAN), remifentanyl infusion of 0.25 µg is started. It continued until the end of the operation.

Main outcome variables

Intraoperative bleeding, pain, surgeon satisfaction

General information

Reason for update

A more accurate record of the study method

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N112**

Registration date: **2021-04-01, 1400/01/12**

Registration timing: **prospective**

Last update: **2021-07-11, 1400/04/20**

Update count: **1**

Registration date

2021-04-01, 1400/01/12

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-23, 1400/02/03

Expected recruitment end date

2021-06-24, 1400/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of remifentanyl and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty

Public title

Comparison of the effect of remifentanyl and dexmedetomidine on surgeon satisfaction from surgical field and bleeding in rhinoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

18-45 years old Patients undergoing rhinoplasty surgery time of surgery is 7-10 days before menstruation time

Exclusion criteria:

Patients with liver dysfunction Renal dysfunction Any known allergy or hypersensitivity to study drugs Abuse of analgesics and any addiction to opioid, Diabetes mellitus Hemorrhagic disease Using anticoagulants Cerebrovascular disease Heart block Cardiovascular disease Morbid obesity Females whom experience nausea and vomiting in their menstrual cycle Revision rhinoplasty surgery

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is based on permutation block randomization method with block size 6 by using the site www.sealedenvelope.com and Seed number: 266608829014794.

Blinding (investigator's opinion)

Single blinded

Blinding description

The drugs are prepared by a nurse who is unaware of the type of study with label A in the dexmedetomidine group and label B in the remifentanyl group and are given to a person who is unaware of the specialization of the groups for injection. The person assessing patients and patient satisfaction at the end of the study is also unaware of the allocation of study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2020-07-19, 1399/04/29

Ethics committee reference number

IR.SUMS.MED.REC.1399.241

Health conditions studied

1

Description of health condition studied

Rhinoplasty surgery

ICD-10 code

Z41.1

ICD-10 code description

Encounter for cosmetic surgery

Primary outcomes

1

Description

Amount of intraoperative bleeding

Timepoint

At the end of the surgery

Method of measurement

Observation

2

Description

Post operative pain

Timepoint

At arrival to the recovery room and at, 45,30,15 minutes

Method of measurement

Visual analogue Scale

Secondary outcomes

1

Description

Patients' satisfactions

Timepoint

After injection of intervention drugs in the recovery room and surgery ward

Method of measurement

Likert Scale

2

Description

Surgeon' satisfactions

Timepoint

At the end of the surgery

Method of measurement

Likert Scale

Intervention groups

1

Description

Intervention group: In the Intervention group one patients will receive 1 µg / kg dexmedetomidine (PFIZER, USA) for 20 minutes and at the same time as induction begins with a dose of 0.6 µg / kg and continues until the end of the operation..

Category

Prevention

2

Description

Intervention group: In the Intervention group two: Simultaneously with the induction of anesthesia, in the remifentanil group (EXIR, IRAN), remifentanil infusion of 0.25 µg is started. It continued until the end of the operation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Maryam Nemati

Street address

Khalili Educational Hospital, Khalili Street -

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3612 2313

Email

khalili.hospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Abbas Rezaianzadeh

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

vcrdep@sums.ac.ir

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

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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Nemati

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code
7134844119
Phone
+98 71 3647 4270
Email
Nemati.mrym@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Reza Jouybar
Position
Cardio-anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Department, Faghihi Hospital, Zand Street
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3647 4270
Email
joybarr@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farzaneh Masihi
Position
MS in English Teaching, BS in anesthesia/English Consultant
Latest degree
Master
Other areas of specialty/work
Anesthesiology
Street address
5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street
City
Shiraz
Province
Fars
Postal code
7134844119
Phone
+98 71 3647 4270
Email
masihifarzaneh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against the policies of the center.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available