

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparing the effect of Dexmedetomidine and Remifentanil of induce controlled hypotension during rhinoplasty

#### Protocol summary

Registration timing: **retrospective**

#### Study aim

Comparison of the effect of Dexmedetomidine and Remifentanil on controlling hypotension during rhinoplasty

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

#### Registration date

2019-07-13, 1398/04/22

#### Design

This study is clinical trial and double blind. 60 patients candidate rhinoplasty in Amirkabir Hospital in Arak will be entered in this study. We will divide patients in 2 groups by simple randomization. Groups are parallel.

#### Registrant information

##### Name

Farzane Farmani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3882 6802

##### Email address

f.farmani@arakmu.ac.ir

#### Settings and conduct

This study is clinical trial and double blind. 60 patients candidate for rhinoplasty in Amirkabir Hospital in Arak will be entered in this study. Outcome assessor and analyzer and participants will not be aware from grouping.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with rhinoplasty referring to Amir Kabir Hospital in Arak, patients aged 18 to 50 years, patients with ASA Class I and II, all patients undergo surgery by one surgeon, the operating time is between 90 to 180 minutes. Exclusion criteria: patients with ASA Classes 3 and 4, patients who have allergies to dexmedetomidine or remifentanil

#### Expected recruitment start date

2019-04-27, 1398/02/07

#### Expected recruitment end date

2019-06-28, 1398/04/07

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

For patients in first group, we will infuse 0.5 micro grams per kilogram in 1 hour Dexmedetomidine and for the second group, infuse 50-100 micro grams per kilogram in 1 hour of Remifentanil.

#### Scientific title

Comparing the effect of Dexmedetomidine and Remifentanil of induce controlled hypotension during rhinoplasty

#### Main outcome variables

Mean of blood pressure, mean of pulse rate, mean of bleeding score, mean recovery time

#### Public title

Comparing the effect of Dexmedetomidine and Remifentanil for induction of controlled hypotension

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190410043231N1**

Registration date: **2019-07-13, 1398/04/22**

during rhinoplasty

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

All patients with rhinoplasty referring to Amir Kabir Hospital in Arak Patients aged 18 to 50 years Patients with ASA class I and II All patients undergo surgery by a surgeon Operating time is between 90 to 180 minutes

##### **Exclusion criteria:**

Patients outside the age range of 18 to 50 years Patients with ASA classes 3 and 4 Patients who have allergies to Dexmedetomidine or Remifentanyl

#### **Age**

From **18 years** old to **50 years** old

#### **Gender**

Both

#### **Phase**

1-2

#### **Groups that have been masked**

- Participant
- Care provider
- Investigator

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Simple individual randomization with envelopes in three groups A and B and C. In this method, some cards will be signed as intervention group 1 and the same number of cards for intervention group 2 and the same number of cards for the control group, then the cards will be mixed. One card will be taken out and its group name will be registered and then card will be returned to the container again. Then the cards will be mixed again and another card will be taken. This process will be continued to reach a random sequence according to sample size.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

This study is double blind. Researcher who complete questionnaire and analyzer and participant will be blind (double blind). Outcome assessor and analyzer and participants will not be aware from grouping. The person evaluating the outcome will be unaware of the grouping. Definition of groups A and B will be available to analyzer and outcome assessor.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

###### **Street address**

Ethics committee, Research center, Payambar Azam complex, Basij Square, Sardasht, Arak

###### **City**

Arak

###### **Province**

Markazi

###### **Postal code**

3848176941

##### **Approval date**

2018-08-19, 1397/05/28

##### **Ethics committee reference number**

IR.ARAKMU.REC.1397.137

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Rhinoplasty

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### **1**

##### **Description**

Mean arterial pressure

##### **Timepoint**

At 15, 30, 45, 60, 90, and 120 minutes after the start of operation

##### **Method of measurement**

Barometer

#### **2**

##### **Description**

Mean of pulse rate

##### **Timepoint**

At 15, 30, 45, 60, 90, and 120 minutes after the start of operation

##### **Method of measurement**

Pulse rate counts

#### **3**

##### **Description**

Mean of recovery time

##### **Timepoint**

Recovery

##### **Method of measurement**

Record time in recovery book

#### **4**

##### **Description**

Mean of bleeding score

#### **Timepoint**

At 15, 30, 45, 60, 90, and 120 minutes after the start of operation

#### **Method of measurement**

Suction and observation of blood gas

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group 1: Dexmedetomidine, 0.5 micro grams per kilogram per hour for infusion during surgery

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Intervention group 2: Remifentanil 50 to100 micro grams per kilogram per hour for infusion during surgery

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Amirkabir hospital

###### **Full name of responsible person**

Farzane Farmani

###### **Street address**

Amirkabir hospital, Parastar square, Shahidshirodi St, Arak

###### **City**

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###### **Postal code**

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###### **Phone**

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###### **Fax**

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###### **Email**

farmanifarzane@yahoo.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Arak University of Medical Sciences

###### **Full name of responsible person**

Mohammad Arjmandzadegan

##### **Street address**

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

##### **City**

Arak

##### **Province**

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##### **Postal code**

3848176341

##### **Phone**

+98 86 3417 3639

##### **Email**

mmatinam81@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Arak 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**

Arak University of Medical Sciences

###### **Full name of responsible person**

Alireza Kamali

###### **Position**

Associate professor

###### **Latest degree**

Specialist

###### **Other areas of specialty/work**

Anesthesiology

###### **Street address**

Shahid Shirodi street, Valiasr square, Valiasr hospital

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###### **Province**

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###### **Postal code**

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###### **Phone**

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###### **Email**

alikaliamir@yahoo.com

### **Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Alireza Kamali

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Farzaneh Farmani

**Position**

Medicine student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

When we publish article in journal

**When the data will become available and for how long**

After the article is published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

If there are additional questions

**From where data/document is obtainable**

Person responsible for the accountability of Dr. Alireza Kamali alikalaliir@yahoo.com

**What processes are involved for a request to access data/document**

Send an e-mail containing the layout specifications to the person responsible for the scientific answer

**Comments**