

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of patient extubation in sitting versus supine position after septoplasty operation in 501 AJA hospital.

Protocol summary

Study aim

Comparison of patient extubation in sitting versus supine position after septoplasty operation in 501 AJA hospital.

Design

Prospective randomized Single blinded Clinical trial study with Simple Random Sampling method using black and white cards (each group was 30)

Settings and conduct

After septoplasty operation in patient who admitted in 501 aja hospital and treated with same method, In one group after the end of the operation and returning the strength of the muscles of the patient, they performed extubation of the tracheal tube in the supine position, and in the other group after observing the relaxation of muscle they performed extubation of tube in the sitting position.

Participants/Inclusion and exclusion criteria

Entry requirements: All patients aged 20-60 years and ASA I who come to the 501 Aja city of Tehran from the time of the approval of the plan for septoplasty with general anesthesia and sign a written consent form for the research project. Conditions of non-arrival: People with ASA in Class III, II and IV, People with bleeding disorder, People with sleep apnea, People with arthritis rheumatoid , especially in the neck area, People with cervical stenosis or disc . Individuals with a right shunt to the heart of patent foramen ovale (PFO) in their history (Risk of Paradoxical Venous Air Embolism).

Intervention groups

In one group after the end of the operation and returning the strength of the muscles of the patient and relaxing the muscle relaxation, they performed extubation of the tracheal tube in the supine position, and in the other group after observing the cases of muscle strength recovery and relaxation of muscle relaxation and after the condition of the sitting to the bed We act to extol the patient

Main outcome variables

Extubation position

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110103005536N7**

Registration date: **2020-07-01, 1399/04/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-01, 1399/04/11**

Update count: **0**

Registration date

2020-07-01, 1399/04/11

Registrant information

Name

Mohamadreza Rafiei

Name of organization / entity

Artesh University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-07-07, 1394/04/16

Expected recruitment end date

2021-01-09, 1399/10/20

Actual recruitment start date

2015-07-07, 1394/04/16

Actual recruitment end date

2021-01-09, 1399/10/20

Trial completion date

2021-01-09, 1399/10/20

Scientific title

Comparison of patient extubation in sitting versus supine position after septoplasty operation in 501 AJA hospital.

Public title

Comparison of patient extubation after septoplasty operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patient in 20-60 years old ASA 1

Exclusion criteria:

patient with ASA II, III, IV hematologic disorders cervical rheumatoid arthritis

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to the Simple Random Sampling method using black and white cards (each group was 30), so that patients with a black card to group one, and patients with a white card The second group is dedicated and this process is repeated again.

Blinding (investigator's opinion)

Single blinded

Blinding description

- Patients undergoing anesthesia awake without knowing where they are being exposed. 2. The person collecting the information that is entered into the room after extubation of the patient and does not know how to extubate the patient. 3. The person analyzing the information that is not present in the operating room and only has access to the encoded information and is not aware of how each patient is extubating.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJA university of medical sciences

Street address

West Fatemi- Etemadzadeh

City

Tehran

Province

Tehran

Postal code

8158177365

Approval date

2015-07-06, 1394/04/15

Ethics committee reference number

IR.AJAUMS.REC.1394.16

Health conditions studied

1

Description of health condition studied

septoplasty

ICD-10 code

J34.2

ICD-10 code description

Deflection or deviation of septum

Primary outcomes

1

Description

Position of extubation

Timepoint

during the intervention

Method of measurement

observation. this parameter evaluates in two position: supine and sitting.

Secondary outcomes

1

Description

systolic blood pressure

Timepoint

during the intervention

Method of measurement

monitoring of patient blood pressure

2

Description

heart rate

Timepoint

during the intervention

Method of measurement

monitoring of patient heart rate

3

Description

Arterial oxygen saturation

Timepoint

during the intervention

Method of measurement

monitoring of patient arterial oxygen saturation

4

Description

Laryngospasm

Timepoint

during the intervention

Method of measurement

clinical

5

Description

Agitation

Timepoint

during the intervention

Method of measurement

Richmond agitation sedation scale (RASS)

6

Description

oral suction

Timepoint

during the intervention

Method of measurement

Count the number of times you need to suction with the device

7

Description

age

Timepoint

before start of intervention

Method of measurement

patient identification card

8

Description

Gender

Timepoint

Before start of intervention

Method of measurement

based on the phenotype

Intervention groups

1

Description

Intervention group: Patients using the Simple Random Sampling sampling method are divided into two groups using black and white cards (30 people per group). In

one group, after the operation and the return of force to the patient's muscles and their muscle relaxation, we perform extubation of the tracheal tube in "supine" position, and cases of decreased arterial oxygen saturation, need for frequent suction, cases of laryngospasm, cases of restlessness in recovery, increased pressure. We record blood and heart rate in patients.

Category

Treatment - Other

2

Description

Intervention group: Patients using the Simple Random Sampling sampling method are divided into two groups using black and white cards (30 people per group). In one group, after the operation and the return of force to the patient's muscles and their muscle relaxation, we perform extubation of the tracheal tube in "sitting" position, and cases of decreased arterial oxygen saturation, need for frequent suction, cases of laryngospasm, cases of restlessness in recovery, increased pressure. We record blood and heart rate in patients.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

501 AJA Hospital

Full name of responsible person

Dr. Mohamadreza Rafiei

Street address

501 AJA hospital, , Etemadzadeh St., west Fatemi Ave.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Saeed Soleyman Meygooni

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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
Artesh 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
Artesh University of Medical Sciences

Full name of responsible person
Dr Mohamadreza Rafiei

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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

All data can be shared after it is unrecognizable

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

All researchers and colleagues in this field

Under which criteria data/document could be used

For the purpose of therapeutic-research purposes and by mentioning the names of the authors of the article

From where data/document is obtainable

Dr. mohamadreza rafiei

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

sending an email to Dr. mohamadreza rafiei

Comments