

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of pleasing olfactory images on the atelectasis in patients with cardiac surgery

Protocol summary

Summary

This study is conducted for evaluating the effects of pleasing olfactory images on the atelectasis in Patients with cardiac surgery in Fatemeh Zahra hospital in Sari. This is a clinical trial in which 80 patients who are candidate for open heart surgery using sternotomy and cardiopulmonary bypass support, randomly allocated to groups of experiment and control. Patients having no: neuromuscular and cognitive disorders; respiratory failure; hemodynamic instability; ejection fraction less than 30 percent; mental retardation; olfactory impairment; preoperative pulmonary disease(pneumonia, chronic obstructive pulmonary disease, atelectasis, pleural effusion and asthma); BMI more than 40 kg/m2; positive history of previous heart or lung surgery; positive history of previous severe trauma to the head or nose and positive history of previous frequent sinus infections will be studied. Patients who are allocated in experiment group will receive planned training before surgery. Designed cards with pictures of rose, banana, apple and lemon placed at their disposal and Will be asked to look at these pictures and Imagine the smell of it in their minds and as much as possible to do deep sniffing. The exercises will be conducted for two hours in the morning and evening during the first and second day after surgery at the awakening. Patients who are allocated in control group will receive the hospital routine treatment. For comparing the outcomes ABG, atelectasis in chest x ray will be compared. Arterial blood gasses will be compared pre operation and first and second day post operation. Chest x ray will be compared pre operation and second day post operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503157494N11**

Registration date: **2015-04-25, 1394/02/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-25, 1394/02/05

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7551

Email address

mbagheri@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Science

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of pleasing olfactory images on the atelectasis in patients with cardiac surgery

Public title

The effects of pleasing olfactory images on the atelectasis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: consent to participate in the study; no emergency surgery(coronary artery bypass and heart valves using sternotomy and cardiopulmonary bypass support); aged 18 years and older; ejection fraction more than 30 percent; having no mental retardation and olfactory impairment; negative history of previous heart or lung surgery; negative history of previous severe trauma to the head or nose; negative history of previous frequent sinus infections; Lack of preoperative pulmonary disease(pneumonia, chronic obstructive pulmonary disease, atelectasis, pleural effusion and asthma); BMI less than 40 kg/m2. Patients with systolic blood pressure less than 90 mm Hg despite additional fluids; PH arterial less than 7.30; arterial carbon dioxide pressure greater than 50 mmHg; arterial oxygen saturation less than 80% despite oxygen; blood hemoglobin concentration of less than 7 g/dL; serum creatinine greater than 3.5 mg/dL were not included in the study. Exclusion criteria: patients' unwillingness to continue cooperation; need for reoperation due to surgery complications; incidence of cognitive and neurological disorders after surgery; postoperative hemodynamic instability(systolic blood pressure below 80 mm Hg); postoperative bleeding more than 500 ml; need for mechanical ventilation for more than 15 hours after surgery.

Age
From **18 years** old

Gender
Both

Phase
2

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

Ethics Committee of Mazandaran University of Medical

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square, Sari, Mazandaran, Iran.

City

Sari

Postal code

4816715793

Approval date

2016-03-03, 1394/12/13

Ethics committee reference number

13/12/1393

Health conditions studied

1

Description of health condition studied

Atelectasis

ICD-10 code

J98.1

ICD-10 code description

Pulmonary collapse

Primary outcomes

1

Description

Atelectasis

Timepoint

Pre & post operation and second day post operatively

Method of measurement

Chest x ray

Secondary outcomes

1

Description

Arterial blood gases

Timepoint

Before surgery; the morning and afternoon of the first day of surgery, before and after the intervention; morning and afternoon of the second day after surgery, before and after the intervention

Method of measurement

Arterial blood gas test(ABG)

2

Description

Systolic and diastolic arterial blood pressure

Timepoint

Before surgery; the morning and afternoon of the first day of surgery, before and after the intervention; morning and afternoon of the second day after surgery, before and after the intervention

Method of measurement

Sphygmomanometer

3

Description

Temperature

Timepoint

Before surgery; the morning and afternoon of the first day of surgery, before and after the intervention; morning and afternoon of the second day after surgery, before and after the intervention

Method of measurement

Oral Thermometer

4

Description

Respiratory rate

Timepoint

Before surgery; the morning and afternoon of the first day of surgery, before and after the intervention; morning and afternoon of the second day after surgery, before and after the intervention

Method of measurement

Number of respiratory rate

5

Description

Heart rate

Timepoint

Before surgery; the morning and afternoon of the first day of surgery, before and after the intervention; morning and afternoon of the second day after surgery, before and after the intervention

Method of measurement

Cardiac monitoring

6

Description

Saturation of Peripheral Oxygen

Timepoint

Before surgery; the morning and afternoon of the first day of surgery, before and after the intervention; morning and afternoon of the second day after surgery, before and after the intervention

Method of measurement

Monitor and pulse oximetry

Intervention groups

1

Description

Patients who are allocated in experiment group will receive planned trainings before surgery. Designed cards with pictures of rose, banana, apple and lemon placed at their disposal and Will be asked to look at these pictures and Imagine the smell of it in their minds and as much as possible to do deep sniffing. The exercises will be conducted for two hours in the morning and evening during the first and second day after surgery at the

awakening

Category

Prevention

2

Description

Patients who are allocated in control group will receive the hospital routine treatment. Any intervention is not done before surgery for this group of patients.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra hospital

Full name of responsible person

Dr Masoumeh Bagheri- Nesami

Street address

Mazandaran University of Medical Sciences, three-way Joibar, highway Basij, Imam square, Sari, Mazandaran, Iran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research Mazandaran University of Medical Sciences.

Full name of responsible person

Dr Ahmad Ali Enayeti

Street address

Vice Chancellor for research Mazandaran University of Medical Sciences, Moalem Street, Moalem Square, Sari, Iran.

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Masumeh Bagheri Nesami

Position

PHD/ faculty member

Other areas of specialty/work

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Mazandaran University of Medical Sciences, three-way Joibar, highway Basij, Imam square, Sari, Mazandaran, Iran.

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Web page address

Person responsible for updating data

Contact

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Masumeh Bagheri Nesami

Position