

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the Effects of Dexmedetomidine and Fentanyl-Midazolam Combination on Mitigating Stress Response for Microlaryngoscopy: A Randomized, Double-Blind, Clinical Trial

Protocol summary

Study aim

This study compared the effect of dexmedetomidine and Fentanyl-Midazolam on attenuation of the hemodynamic stress response in patients scheduled for microlaryngoscopy.

Design

Double-blind, randomized, clinical trial with 2 intervention groups, with parallel groups, on 60 patients.

Settings and conduct

Candidates for Microlaryngoscopy in Magrabi Eye, ENT and Dental Center, Doha, Qatar are divided into 2 groups. The groups are parallel. The trial phase is 2-3.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65 years ASA grade I/III
Scheduled for microlaryngoscopy
Exclusion criteria: patients with known allergy to study drugs
Coronary artery disease
Pulmonary disease
Arrhythmia
Pregnancy
Renal impairment

Intervention groups

Group I: 1 µg/kg of dexmedetomidine over 10 minutes before anesthesia induction followed by 0.05 mg/kg/h as infusion after anesthesia induction (group D).
Group II: 0.8 µg/kg fentanyl plus 0.05 mg/kg midazolam over 10 minutes before anesthesia induction followed by 1 µg/kg/h fentanyl and 0.05 mg/kg/h midazolam as infusion after anesthesia induction (group MF)

Main outcome variables

Hemodynamic stress response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210117050057N2**

Registration date: **2021-03-19, 1399/12/29**

Registration timing: **prospective**

Last update: **2021-03-19, 1399/12/29**

Update count: **0**

Registration date

2021-03-19, 1399/12/29

Registrant information

Name

Mohamed Oriby

Name of organization / entity

Faculty of Medicine, Tanta University

Country

Egypt

Phone

+20 3 3059056

Email address

oraiby500@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-25, 1400/01/05

Expected recruitment end date

2021-06-01, 1400/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Dexmedetomidine and Fentanyl-Midazolam Combination on Mitigating Stress Response for Microlaryngoscopy: A Randomized, Double-Blind, Clinical Trial

Public title

Comparison of the Effects of Dexmedetomidine and

Fentanyl-Midazolam Combination on Mitigating Stress Response for Microlaryngoscopy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-65 years ASA grade I/III Scheduled for microlaryngoscopy
Exclusion criteria:
Patients with known allergy to study drugs Coronary artery disease Pulmonary disease Arrhythmia Pregnancy Renal impairment

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to one of two groups using computer-generated software of randomization introduced into sealed opaque envelopes which are sequentially numbered.

Blinding (investigator's opinion)
Double blinded

Blinding description
An independent nurse, who did not participate in the study or data collection prepared all study drugs. These drugs were administered by another nurse who was blind to the study and the groups. The anesthesiologist, surgeon and data collectors were all blinded to the given study drugs and the envelopes were opened immediately before administration by a person who did not participate in the observation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board (IRB) of Magrabi Eye & ENT

Center
Street address
D ring road
City
Doha
Postal code
23293
Approval date
2021-03-13, 1399/12/23
Ethics committee reference number
MEEC-IRB- 2021-103

Health conditions studied

1

Description of health condition studied

Microlaryngoscopy

ICD-10 code

J38.7

ICD-10 code description

Other diseases of larynx

Primary outcomes

1

Description

Hemodynamic stress response

Timepoint

Intraoperative

Method of measurement

Systolic Blood Pressure , Mean Arterial Pressure, Heart Rate were monitored

Secondary outcomes

1

Description

Intraoperative requirement of propofol

Timepoint

Intraoperative

Method of measurement

Total dose guided by bispectral index

2

Description

Sedation

Timepoint

Postoperative

Method of measurement

Ramsay score

3

Description

Analgesia

Timepoint

Postoperative

Method of measurement

4**Description**

Anesthesia duration

Timepoint

Intraoperative

Method of measurement

Time measurement

5**Description**

Recovery time

Timepoint

Postoperative

Method of measurement

Time measurement

Intervention groups**1****Description**

Dexmedetomidine group: 30 patients who received 1 µg/kg of dexmedetomidine over 10 minutes before anesthesia induction followed by 0.05 mg/kg/h as infusion after anesthesia induction

Category

Treatment - Drugs

2**Description**

Fentanyl-Midazolam group: 30 patients received fentanyl 0.8 µg/kg plus midazolam 0.05 mg/kg over 10 minutes before anesthesia induction followed by 1 µg/kg/h fentanyl and 0.05 mg/kg/h midazolam as infusion after anesthesia induction

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Magrabi Eye, ENT and Dental Center, Doha, Qatar

Full name of responsible person

MOHAMED ORIBY

Street address

D ring road

City

Doha

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23293

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+974 4437 5046

Email

oraiby500@hotmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Magrabi Eye, ENT and Dental Center, Doha, Qatar

Full name of responsible person

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D ring road

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Doha

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Phone

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Email

oraiby500@hotmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Magrabi Eye, ENT and Dental Center, Doha, Qatar

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Faculty of Medicine, Tanta University

Full name of responsible person

MOHAMED ORIBY

Position

Lecturer of Anesthesiology

Latest degree

Ph.D.

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available