

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of lidocaine solution versus dexmedetomidine on gag reflex during propofol-based sedation for patients undergoing upper gastrointestinal endoscopy

Protocol summary

Study aim

Determining the effectiveness of lidocaine solution and dexmedetomidine on gag reflex in upper endoscopy patients under anesthesia with propofol

Design

Clinical trial, with parallel groups, without blinding, phase three, randomized, which will be conducted on 126 patients randomly.

Settings and conduct

The studied population are patients aged 18-60 who are candidates for endoscopy, referring to Ayatollah Rouhani Babol educational and therapeutic center. Patients are randomly divided into three intervention groups using a computer and the intervention will be performed on them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-60 years and American Society of Anesthesiologists Classification (ASA class) 1-2
Exclusion Criteria: cardiovascular diseases; respiratory diseases; mental-psychological diseases; patients with a history of allergies and emergency patients.

Intervention groups

Intervention group1: 50 mg of propofol (Shefafarmed) slowly intravenously over 1 minute. Intervention group2:At First, 0.5 micrograms/Kg along with dexmedetomidine (Arang Daro) intravenously, followed by 50 mg of propofol (Shefafarmed) intravenously within 1 minute. Intervention group3: 1cc of lidocaine solution (Elixir Pharmaceuticals) 2% 3 to 5 minutes before endoscopy by pushing aside the tongue with the help of a sling in the pharynx area.

Main outcome variables

Gag Reflex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190928044907N5**
Registration date: **2023-09-28, 1402/07/06**
Registration timing: **prospective**

Last update: **2023-09-28, 1402/07/06**

Update count: **0**

Registration date

2023-09-28, 1402/07/06

Registrant information

Name

seyed hossein hamidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3222 3301

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a.hamidi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2024-04-29, 1403/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lidocaine solution versus dexmedetomidine on

gag reflex during propofol-based sedation for patients undergoing upper gastrointestinal endoscopy

Public title

Determining the effectiveness of lidocaine solution and dexmedetomidine on gag reflex

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-60 years American Society of Anesthesiologists Classification (ASA class) 1-2

Exclusion criteria:

Cardiovascular Diseases Respiratory Diseases Mental illnesses Patients with a history of allergies Emergency patients

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using permutation blocks of size 6. (AABBCC) in such a way that the blocks of 6 consist of random combinations of 2 to A (Propofol), B (Dexmedetomidine) and C (Propofol+Lidocaine). will be randomly assigned to three groups of 42 people. Creating a random sequence in the blocks will be done by a statistician.

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 Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2023-09-17, 1402/06/26

Ethics committee reference number

IR.MUBABOL.HRI.REC.1402.095

Health conditions studied

1

Description of health condition studied

Gag Reflex

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Gag Reflex

Timepoint

5, 10 and 15 minutes after the endoscope is removed from the patient's mouth

Method of measurement

Criteria for measuring the severity of nausea: No nausea: No gag during contact with high risk surfaces of the mouth such as soft palate and tonsils Hakm: Gag formation during contact with high risk surfaces of the mouth such as soft palate and tonsils Medium: Gag formation during contact with low levels Risk of mouth such as hard palate and hard floor: Creating a gag before contact with an abscess, such as when opening the mouth and seeing an abscess

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: 50 mg of propofol (Shefafarmed) slowly intravenously over 1 minute

Category

Treatment - Drugs

2

Description

Intervention group2: At First, 0.5 micrograms/Kg along with dexmedetomidine (Arang Daro) intravenously, followed by 50 mg of propofol (Shefafarmed) intravenously within 1 minute.

Category

Treatment - Drugs

3

Description

Intervention group3: 1cc of lidocaine solution (Elixir Pharmaceuticals) 2% 3 to 5 minutes before endoscopy by pushing aside the tongue with the help of a sling in the pharynx area.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Seyed Hossein Hamidi

Street address

Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Seyed Hossein Hamidi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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