

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the sedation effect of propofol with lidocaine spray versus isolated propofol admission during upper GI endoscopy in elective and outpatient patients

Protocol summary

Study aim

Comparison of the sedative effect of propofol with lidocaine spray and propofol alone in upper gastrointestinal endoscopy

Design

A randomized clinical trial without control group, with parallel groups, phase 3. without blindness that, 160 patients randomly divided into two groups of 80 subjects with block sizes of 4 and 6.

Settings and conduct

The population of this study was aged 20-65 years old who referred to Ayatollah Rouhani Hospital in Babol. Patients randomly divided into two Intervention groups with block sizes of 4 and 6. Intervention group1: propofol (Razavi Pharmacy) at a dose of 50 µg/kg Intervention group2: propofol at a dose of 50 µg/kg and a total of 3 puffs of 10% lidocaine spray (Caspian Tamin company) to the throat and to the tip of the endoscope tube

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients aged 20 to 65 years Patients requiring upper gastrointestinal endoscopy Exclusion criteria: Psychological disease, Addiction, Anemia, Obesity, Swallowing Disorders (Myasthenia gravis and Alzheimer's), Cardiac Disease, Low blood pressure, Bradycardia, Hepatic Failure, Kidney Disease.

Intervention groups

Intervention group1: propofol (Razavi Pharmacy) at a dose of 50 µg/kg Intervention group2: propofol at a dose of 50 µg/kg and a total of 3 puffs of 10% lidocaine spray (Caspian Tamin company) to the throat and to the tip of the endoscope tube

Main outcome variables

Dosage of propofol: nausea, vomiting: instability of vital signs: respiratory distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200526047573N1**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **retrospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

Registration date

2020-10-20, 1399/07/29

Registrant information

Name

Alma Bigdeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8301

Email address

dr.a.bigdeli67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-20, 1399/02/31

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

2020-04-20, 1399/02/01

Actual recruitment end date

2020-06-21, 1399/04/01

Trial completion date

2020-06-21, 1399/04/01

Scientific title

Comparison of the sedation effect of propofol with lidocaine spray versus isolated propofol admission during upper GI endoscopy in elective and outpatient patients

Public title

The effect of lidocaine spray to decrease propofol dosage

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient age between 20 to 65 years old Patients requiring upper gastrointestinal endoscopy

Exclusion criteria:

Psychological disease Addiction Anemia Obesity Swallowing Disorders (Myasthenia gravis and Alzheimer's) Cardiac Disease Low blood pressure Bradycardia Hepatic Failure Kidney Disease

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Actual sample size reached: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly divided into two groups. In this study, coin toss will be used to generate a random sequence in the trial. So that one of the study groups is head and the other is the tail, and based on the sample size, the same number of coins will be thrown, and the individuals will be randomly assigned to two groups.

Group tail patients will be treated with propofol with lidocaine spray and heads treated with propofol

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

Babol Medical University., Ganj Afrouz Blvd., Babol Town,

City

Babol

Province

Mazandaran

Postal code

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Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.346

Health conditions studied

1

Description of health condition studied

Diseases of upper digestive system which need endoscopy

ICD-10 code

K25

ICD-10 code description

Gastric ulcer

Primary outcomes

1

Description

Propofol Dosage

Timepoint

At The End of Endoscopy

Method of measurement

Milligram per kilogram

2

Description

Nausea and Vomiting

Timepoint

At The End of Endoscopy

Method of measurement

Patient's clinical symptoms

3

Description

Respiratory Distress

Timepoint

At The End of Endoscopy

Method of measurement

Intercostal muscle retraction

4

Description

Heart Rate

Timepoint

At The End of Endoscopy

Method of measurement

Cardiac monitoring

5

Description

Blood Pressure

Timepoint

At The End of Endoscopy

Method of measurement

Non Invasive Blood Pressure Tools

Secondary outcomes

empty

Intervention groups

1

Description

propofol (Razavi Pharmacy) at a dose of 50 µg/kg

Category

Treatment - Drugs

2

Description

propofol at a dose of 50 µg/kg and a total of 3 puffs of 10% lidocaine spray (Caspian Tamin company) to the throat and to the tip of the endoscope tube

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouhani Hospital

Full name of responsible person

Alma Bigdeli

Street address

Rohani Hospital., Ganj Afrouz Blvd.,Babol Town.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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rezaghadimi@yahoo.com

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

Alma Bigdeli

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Public Health

Street address

Rohani Hospital., Ganj Afrouz Blvd.,Babol Town.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Resident

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable