

# 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

۴۷۱۷۴۴۷۷۴۵

#### 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.

##### City

Babol

##### Province

Mazandaran

##### Postal code

۴۷۱۷۶۴۷۷۴۵

##### Phone

+98 11 3223 8301

##### Email

Ficu\_ss@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Reza Ghadimi

#### Street address

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

#### City

Babol

#### Province

Mazandaran

#### Postal code

۴۷۱۷۶۴۷۷۴۵

#### Phone

+98 11 3223 8301

#### Email

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.

##### City

Babol

##### Province

Mazandaran

##### Postal code

۴۷۱۷۶۴۷۷۴۵

##### Phone

+98 11 3223 8301

##### Email

dr.a.bigdeli67@gmail.com

## Person responsible for scientific 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.

**City**

Babol

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶۴۷۷۴۵

**Phone**

+98 11 3223 8301

**Email**

dr.a.bigdeli67@gmail.com

**Person responsible for updating data**

**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.

**City**

Babol

**Province**

Mazandaran

**Postal code**

۴۷۱۷۶۴۷۷۴۵

**Phone**

+98 11 3223 8301

**Email**

dr.a.bigdeli67@gmail.com

**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