

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of the effectiveness of Dexmedtomidine and propofol during ERCP

Protocol summary

Study aim

Comparison of the effectiveness of Dexmedtomidine and propofol during ERCP

Design

Clinical trial, with two intervention and control arms in parallel with random allocation and without blinding

Settings and conduct

The study population are ERCP candidate patients referred to Babol Educational and Medical Center who are randomly assigned to intervention and control groups after initial evaluations of the inclusion criteria. After the sedation intervention before the procedure, 5 minutes after the start, 15 minutes after the start of the procedure and after finishing the work with the Ramsay score tool is measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65 years old; Absence of cardiovascular disease; ERCP candidate patients; Do not take sedatives; Absence of blood pressure; Absence of respiratory disease; Body Mass Index < 30
Exclusion criteria: History of drug abuse; Medical allergy; Kidney disease; Liver disease; Pregnancy

Intervention groups

Control group: Fentanyl at a dose of one microgram per kilogram of body weight up to a maximum of 100 micrograms with first receiving 1 mg per kilogram of body weight of propofol as STAT and then receiving a dose of 50 macro per kilogram per minute maintenance drug. Intervention group: Fentanyl at a dose of one microgram per kilogram of body weight up to a maximum of 100 micrograms with a maintenance dose of dexmedetomidine at a dose of 1 microgram per kilogram of body weight per hour

Main outcome variables

Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190928044907N4**

Registration date: **2021-08-27, 1400/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-27, 1400/06/05**

Update count: **0**

Registration date

2021-08-27, 1400/06/05

Registrant information

Name

seyed hossein hamidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3222 3301

Email address

a.hamidi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-10-02, 1400/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Dexmedtomidine and propofol during ERCP

Public title

The effectiveness of Dexmedetomidine and propofol during ERCP

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18-65 years old
Absence of cardiovascular disease
ERCP candidate patients
Do not take sedatives
Absence of blood pressure
Absence of respiratory disease
Body Mass Index < 30

Exclusion criteria:

History of drug abuse
Medical allergy
Kidney disease
Liver disease
Pregnancy

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups of 40 using 4 blocks and 20 blocks with a ratio of 1: 1. In order to generate the allocation sequence, the free website www.randomization.com will be used. The notes will be written on separate sheets and will be placed in sealed envelopes and will be given to the principal investigator for study.

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**

The Ethics Committee of Babol University of Medical Sciences

Street address

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.MUBABOL.REC.1399.487

Health conditions studied**1****Description of health condition studied**

Sedation

ICD-10 code

T88.52

ICD-10 code description

Failed moderate sedation during procedure

Primary outcomes**1****Description**

Heart Rate

Timepoint

Before starting the procedure, 5 minutes after starting, 15 minutes after starting the procedure and after finishing the work.

Method of measurement

Number per minute

2**Description**

O2 saturation

Timepoint

Before starting the procedure, 5 minutes after starting, 15 minutes after starting the procedure and after finishing the work.

Method of measurement

Pulse oximeter

3**Description**

Sedation

Timepoint

Before starting the procedure, 5 minutes after starting, 15 minutes after starting the procedure and after finishing the work.

Method of measurement

Ramsay score

Secondary outcomes

empty

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

Control group: : Fentanyl at a dose of one microgram per

kilogram of body weight up to a maximum of 100 micrograms with first receiving 1 mg per kilogram of body weight of propofol as STAT and then receiving a dose of 50 macro per kilogram per minute maintenance drug

Category

Treatment - Drugs

2

Description

Intervention group: Fentanyl at a dose of one microgram per kilogram of body weight up to a maximum of 100 micrograms with a maintenance dose of dexmedetomidine at a dose of 1 microgram per kilogram of body weight per hour

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

Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

s.hosseinhamidi@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

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3219 7667

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

Seyed Hossein Hamidi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

s.hosseinhamidi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Seyed Hossein Hamidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ayatollah Rouhani Hospital, Daneshgah Square,
Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

s.hosseinhamidi@yahoo.com

Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

s.hosseinhamidi@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Seyed Hossein Hamidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Ayatollah Rouhani Hospital, Daneshgah Square,

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no plan for its publish

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available