

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Assessment of epinephrine spray versus placebo for prevention from acute pancreatitis following endoscopic retrograde colangiopancreatography (ERCP)

#### Protocol summary

##### Study aim

Evaluation of epinephrine spray efficacy versus placebo in prevention of acute pancreatitis following ERCP

##### Design

A double-blinded randomized parallel clinical trial with a control group in phase 1 on 140 patients using random allocation table for the randomization

##### Settings and conduct

The study was conducted on all patients referred to ALzahra Hospital affiliated at Isfahan University of Medical Sciences until achieving the desired number of patients. Only the nurse responsible for injections during ERCP was aware of the remedies, and the physician, the patient, were unaware.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age above 18 years old, candidate for ERCP due to any reason and willingness for participation in the study  
Unmet criteria: contraindication for treatment with epinephrine (hyperthyroidism, cardiac arrhythmia), uncontrolled ischemic cardiac disease, previous history of acute or chronic pancreatitis, previous history of pancreatic duct manipulation

##### Intervention groups

All patients underwent ERCP based on standard protocols. The intervention group was treated with 20 ml epinephrine spray 0.02% (Darupakhsh Company; Iran) on the papilla for a minute and the control group was treated with normal saline spray similar in volume and duration of spraying.

##### Main outcome variables

Amylase and lipase level within 24 hours after ERCP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201128049521N1**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **retrospective**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

##### Registration date

2020-12-15, 1399/09/25

##### Registrant information

###### Name

Laleh Raeisi Bidakani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3444 7707

###### Email address

raesibidakanilaleh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-06-22, 1398/04/01

##### Actual recruitment start date

2018-09-23, 1397/07/01

##### Actual recruitment end date

2019-11-16, 1398/08/25

##### Trial completion date

2019-11-16, 1398/08/25

##### Scientific title

Assessment of epinephrine spray versus placebo for prevention from acute pancreatitis following endoscopic retrograde colangiopancreatography (ERCP)

**Public title**

Prevention of pancreatitis by epinephrine spray after endoscopic retrograde cholangiopancreatography

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Over 18 years old of age Indication for ERCP due to any etiology Willingness for participation in the study

**Exclusion criteria:**

Any contraindication for epinephrine administration (hyperthyroidism, cardiac arrhythmia) Uncontrolled cardiac ischemic disease Previous history of acute and chronic pancreatitis Previous history of pancreatic duct manipulation

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **140**

Actual sample size reached: **124**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients were gathered until achieving the desired number of the study population. Randomization was done through simple sampling, in individual units. Each of the patients was provided with a sealed envelope. Prior to the intervention, the envelope was unwrapped by the nurse and the desired intervention was done. The physician was blinded about the type of intervention.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The nurse responsible for injections during ERCP was the only person aware of the remedy, but the patient and the physician were not.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical

Sciences

**Street address**

Hezarjarib Street, Isfahan Univeristy of Medical Sciences, Isfahan, Iran

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2017-06-08, 1396/03/18

**Ethics committee reference number**

IR.MUI.REC.1396.3.184

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

Acute pancreatitis

**ICD-10 code**

K85

**ICD-10 code description**

Acute pancreatitis

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

Increase in blood amylase

**Timepoint**

At baseline and within 24 hours after ERCP

**Method of measurement**

Blood sample

**2****Description**

Increase in blood lipase

**Timepoint**

At baseline and within 24 hours after ERCP

**Method of measurement**

Blood sample

**Secondary outcomes**

empty

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

Intervention group: By the end of the procedure, 20 ml of epinephrine 0.02% (Darupakhsh; Iran) was sprayed on the papilla for a minute.

**Category**

Prevention

## 2

### Description

Control group: By the end of the procedure, 20 ml normal saline was sprayed on the papilla for a minute

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra Hospital

##### Full name of responsible person

Laleh Raeisi Bidakani

##### Street address

Alzahra Hospital, Shohadayeh Sofe Avenue

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3620 2020

##### Email

raesibidakanilaleh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

لاله رئیس بی‌دکانی

##### Street address

Isfahan University of Medical Sciences, Hezarjarib Avenue

##### City

Isfahan

##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3668 0048

##### Email

raesibidakanilaleh@gmail.com

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Laleh Raeisi Bidakani

##### Position

Internal Medicine Professionalist

##### Latest degree

Specialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

Hezarjarib Avenue, Isfahan University of Medical Sciences, Isfahan, Iran

##### City

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##### Province

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##### Postal code

8196136573

##### Phone

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Laleh Raeisi Bidakani

##### Position

Internal Medicine Professionalist

##### Latest degree

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##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Laleh Raeisi Bidakani

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All the data of the study are available after the documentation and publication of the study

### When the data will become available and for how long

Following the publication of the study

### To whom data/document is available

The university students who design a similar studies

### Under which criteria data/document could be used

For publication of similar articles and by coordination with the tutor

### From where data/document is obtainable

They should be in touch with the tutor using email

### What processes are involved for a request to access data/document

After connection with the tutor and by his acceptance the data is available

### Comments