

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Evaluation the effectiveness of epinephrine spray on papillae in prevention of post-Endoscopic retrograde cholangiopancreatography(ERCP) pancreatitis

Protocol summary

Study aim

Determining of the effectiveness of epinephrine spray on papillae in prevention of post-Endoscopic retrograde cholangiopancreatography(ERCP) pancreatitis

Design

A randomized, double-blinding clinical trial, with the parallel groups, Phase 3 on 164 patients

Settings and conduct

In this randomized double-blind clinical trial, 164 eligible patients referred to Hajar and Ayatollah-Kashani hospitals will be included in the study and randomly divided into two groups. In one group epinephrine spray and the other group, the normal-saline spray will be prescribed. It should be noted that the patient, researcher, and statistical analyst will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age 18 years or older, having intact papillae, no deformity Papilla, consent to participate in the study. Exclusion criteria include having acute pancreatitis, having chronic pancreatitis with an acute exacerbation, above normal serum amylase level or lipase level (> 200 units per liter), having bile duct cancer, previous ERCP history or papilla manipulation and allergy to epinephrine.

Intervention groups

Intervention group: Patients in this group receive 50 mg indomethacin suppository, before the ERCP. In addition, during ERCP and before cannulation, the epinephrine is sprayed locally on the major papillae by a sprinkler catheter and then completely removed from the patient after the endoscope intervention. Control group: Patients in this group receive 50 mg indomethacin suppository, before the ERCP. In addition, during ERCP and before cannulation, the normal saline is sprayed locally on the major papillae by a sprinkler catheter and then completely removed from the patient after the

endoscope intervention.

Main outcome variables

Frequency of cannulation, incidence of pancreatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N35**

Registration date: **2021-06-11, 1400/03/21**

Registration timing: **prospective**

Last update: **2021-06-11, 1400/03/21**

Update count: **0**

Registration date

2021-06-11, 1400/03/21

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-20, 1400/03/30

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of epinephrine spray on papillae in prevention of post-Endoscopic retrograde cholangiopancreatography(ERCP) pancreatitis

Public title

The effectiveness of epinephrine spray on papillae for prevention of pancreatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 years or older Having an intact papillae No deformity Papilla Consent to participate in the study

Exclusion criteria:

Having acute pancreatitis Having chronic pancreatitis with an acute exacerbation Above normal serum amylase level or lipase level (> 200 units per liter) Having bile duct cancer Previous ERCP history or papilla manipulation Allergy to epinephrine

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 164 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". These numbers are randomly labeled A (Control group) and B (Intervention group). Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups A or B.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the two sprays of epinephrine and normal saline of the same color and shape are prepared by the pharmacist and placed in coded packages and given to the doctor. He prescribes them without knowing the type of each drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahre-Kord University of Medical Sciences

Street address

Shahrekord University Of Medical Sciences, Kashani Blvd

City

Shahrekord

Province

Isfahan

Postal code

8815713471

Approval date

2020-11-23, 1399/09/03

Ethics committee reference number

IR.SKUMS.REC.1399.191

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

Biliary pancreatitis

ICD-10 code

K85.1

ICD-10 code description

Biliary acute pancreatitis

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

Frequency of cannulation

Timepoint

24 hours after ERCP operation

Method of measurement

Observation

2**Description**

Incidence of pancreatitis

Timepoint

24 hours after ERCP operation

Method of measurement

Examination and testing of amylase lipase

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients in this group receive 50 mg indomethacin suppository, before the ERCP. In addition, during ERCP and before cannulation, the normal saline is sprayed locally on the major papillae by a sprinkler catheter and then completely removed from the patient after the endoscope intervention.

Category

Placebo

2

Description

Intervention group: Patients in this group receive 50 mg indomethacin suppository, before the ERCP. In addition, during ERCP and before cannulation, the epinephrine is sprayed locally on the major papillae by a sprinkler catheter and then completely removed from the patient after the endoscope intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Mohammad Karami

Street address

Shahrekord University of Medical Sciences, Kashani street,

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2

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Mohammad Karami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Karami

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahrekord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Karami

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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 no further information

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