Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Isfehan
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,
City
Sharekord
Province
Isfehan
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
Email
res.med@skums.ac.ir

2

Recruitment center
Name of recruitment center
Hajar Hospital
Full name of responsible person
Mohammad Karami
Street address
Parastar Street
City
Sharekord
Province
Isfehan
Postal code
88155571
Phone
+98 38 3222 5505
Fax
Email
res.med@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Mohammad Karami
Street address
Vice Chancellory for research, Shahrekord University Of Medical Sciences, Kashani Blvd
City
Shahrekord
Province
Isfehan
Postal code
8815713471
Phone
+98 38 3334 2414
Fax
Email
vcrt@skums.ac.ir
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
Street address
Shahrekord University of Medical Sciences, Kashani street,
City
Shahrekord
Province
Isfehan
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
Email
Bahman_salem@yahoo.com

Person responsible for scientific 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
Street address
Shahrekord University of Medical Sciences, Kashani street,
City
Shahrekord
Province
Isfehan
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
Email
Bahman_salem@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Bahman Salemi
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Shahrekord University of Medical Sciences, Kashani street,
City
Shahrekord
Province
Isfehan
Postal code
8815713471
Phone
+98 38 3333 0061
Fax
Email
Bahman_salem@yahoo.com

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