Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of adding octreotide to indomethacin compared to indomethacin alone in preventing pancreatitis after ERCP in high-risk patients: a randomized clinical trial

Protocol summary

Study aim

The primary objective of this randomized clinical trial is to assess the efficacy of rectal indomethacin alone compared to the combination of rectal indomethacin with intravenous octreotide in preventing pancreatitis following Endoscopic Retrograde Cholangiopancreatography (ERCP) in high-risk patients.

Design

In this clinical trial with parallel groups, 88 patients with inpatient indications after ERCP will be randomly assigned to indomethacin + octreotide (study group) and indomethacin alone (control group) using block randomization. Allocation will be done 1:1 with blocks of size four.

Settings and conduct

Study location: the gastroenterology department of Ghaem and Imam Reza teaching hospitals in Mashhad; Population of study: high-risk patients for development of post ERCP pancreatitis; Blinding: there will be no blinding in present study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 75 years; normal levels of amylase and lipase before undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP); Presence of high-risk criteria for post-ERCP pancreatitis. Exclusion criteria: Pregnancy; breastfeeding; Known hypersensitivity to somatostatin; Use of medications that may interfere with the effects of somatostatin; significant comorbidities

Intervention groups

Intervention group (Indomethacin + octreotide): Octreotide will be infused 100 micrograms intravenously during ERCP as a state and then 50 micrograms intravenously every six hours for 48 hours. Indomethacin 100 mg will be administered rectally at the same time as ERCP. Control group (Indomethacin alone): Indomethacin 100 mg will be administered rectally at the same time as ERCP.

Main outcome variables

Frequency of post-ERCP pancreatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240302061146N1**
Registration date: **2024-04-05, 1403/01/17**
Registration timing: **prospective**

Last update: **2024-04-05, 1403/01/17**
Update count: **0**

Registration date

2024-04-05, 1403/01/17

Registrant information

Name

Roham Gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3854 3031

Email address

dr_rgholami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of adding octreotide to indomethacin compared to indomethacin alone in preventing pancreatitis after ERCP in high-risk patients: a randomized clinical trial

Public title
Octreotide and indomethacin in the prevention of post ERCP pancreatitis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Participants aged between 18 and 75 years Participants with normal levels of amylase and lipase before undergoing Endoscopic Retrograde Cholangiopancreatography (ERCP). Presence of high-risk criteria for post-ERCP pancreatitis based on UpToDate recommendations Multiple cannulations during ERCP History of previous pancreatitis following ERCP Dysfunction of type one and two sphincter of Oddi Repeated injection of contrast material or other fluids into the main pancreatic duct Balloon dilation of an intact biliary sphincter Pancreatic sphincterotomy.
Exclusion criteria:
Pregnancy or breastfeeding Known hypersensitivity to somatostatin Liver or kidney failure Referral with manifestations of an episode of acute pancreatitis or chronic pancreatitis Use of antibiotics, antacids, and other medications that may interfere with the effects of somatostatin History of previous angina, myocardial infarction, or cerebral ischemia within the past three months
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Allocation will be conducted in a 1:1 ratio using blocks of size 4 (AABB, ABAB, ABBA, BAAB, BABA, BBAA). Each generated block will be assigned a specific number. A random order of the blocks will be created by utilizing an online randomization tool such as randomizer.org (https://www.randomizer.org). Allocation of patients to study groups will be done using sealed envelopes.
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
Research Ethics Committee of the Faculty of Medicine, Mashhad University of Medical Sciences
Street address
Faculty of Medicine, Eastern Door of University Campus, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2024-01-16, 1402/10/26
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.461

Health conditions studied

1

Description of health condition studied
Acute pancreatitis following endoscopic retrograde cholangiopancreatography
ICD-10 code
K85.9
ICD-10 code description
Acute pancreatitis, unspecified

Primary outcomes

1

Description
Occurrence of post-ERCP pancreatitis
Timepoint
After 5 hours, and after 10 hours following ERCP
Method of measurement
Obtaining a medical history in terms of abdominal pain along with measuring serum levels of amylase and lipase

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Indomethacin + octreotide group): Octreotide will be infused 100 micrograms intravenously during ERCP as a state and then 50 micrograms intravenously every six hours for 48 hours. Indomethacin 100 mg will be administered rectally at the same time as ERCP.
Category
Treatment - Drugs

2

Description
Control group (Indomethacin alone group): Indomethacin 100 mg will be administered rectally at the same time as ERCP.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr Roham Gholami
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Ebne Sina Street
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2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr Roham Gholami
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Ghaem Hospital, Ahmadabad Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Research and Technology Vice-Chancellor, Qurashi Building, Daneshgah Street.
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Email
vcresraech@mums.ac.ir
Web page address
https://v-research.mums.ac.ir/
Grant name
Grant code / Reference number
۴۰۲۰۲۹۹
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Roham Gholami
Position
Felowship
Latest degree
Specialist
Other areas of specialty/work

Internal Medicine
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Person responsible for updating data

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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
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