Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of indomethacin suppository plus oral CoQ10 verusus indomethacin suppository in prevention of post Endoscopic Retrograde Cholangio-pnacreatography pancreatitis

Protocol summary

Study aim
Comparing the effect of single dose of rectal Indomethacin plus CoQ10 tablet versus single dose of rectal indomethacin on prevention of post Endoscopic Retrograde cho;angio-pancreatography pancreatitis

Design
A randomized, controlled clinical trial with a parallel group on 200 patients.

Settings and conduct
This trial will be done in Endoscopy ward of Talighani hospital, Tehran.200 patients with indication of Endoscopic Retrograde Cholangiopancreatography will be considered for the study. All patients will recieve 100 mg indomethacin rectally just before doing procedure. Patients devided in two groups; to receive the CoQ10 or nothing. Patients in the CoQ10 group received two tablets of 100 mg CoQ10 two hours before doing Cholangiopancreatography. All patients were followed-up for occurrence of post Endoscopic Retrograde Cholangiopancreatography pancreatitis. Endoscopic Retrograde Cholangiopancreatography pancreatitis will defined severe abdominal pain that necessitate hospitalization of a minimum of 48 hours and an elevated serum amylase/serum lipase level of more than 3 times the upper limit of normal.The rate of pancreatitis will be compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 200 patients who undergo Endoscopic Retrograde Cholangiopancreatography between 20 to 80 years old and by taking consent inform will be enrolled in this study. Exclusion criteria: patients with history of hypersensitivity to each of indomethacin or CoQ10.

Intervention groups
Group1: Adminstration of single dose of 100 mg rectal indomethacine just before plus oral coQ10 200 mg two hours before doing Endoscopic cholangiopancreatography Group2: Administration of single dose of 100 mg rectal indomethacin just before doing Endoscopic cholangiopancreatography

Main outcome variables
Pancreatitis occurence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121021011192N13**
Registration date: **2022-09-28, 1401/07/06**
Registration timing: **prospective**

Last update: **2022-09-28, 1401/07/06**
Update count: **0**

Registration date
2022-09-28, 1401/07/06

Registrant information

Name
Mohammad Abbasinazari
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8887 3704
Email address
m_abbasi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-01, 1401/07/09

Expected recruitment end date
2022-12-30, 1401/10/09

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of indomethacin suppository plus oral CoQ10 verusus indomethacin suppository in prevention of post Endoscopic Retrograde Cholangio-pnacreatography pancreatitis

Public title
Comparing the rectal Indomethacin plus oral coQ10 versus rectal indomethacin on prevention of post Endoscopic Retrograde Cholangio-pnacreatography pancreatitis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing ERCP in Taleghani hospital by taking written consent
Exclusion criteria:
Patients history of hypersensitivity against each of indomethacin or coQ10 History of sphinctrotomy
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Ethics committee of pharmacy, nursing and midwifery of Shahid Beheshti university of medical science
Street address
School of Pharmacy, Nyayesh junction, Valiasr street
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2022-08-09, 1401/05/18
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.091

Health conditions studied

1

Description of health condition studied
pancreatitis
ICD-10 code
Other acut
ICD-10 code description
K85.8

Primary outcomes

1

Description
Pancreatitis
Timepoint
10 days after doing Endoscopic Retrograde Cholangio-pancreatography
Method of measurement
clinical evaluation

Secondary outcomes

1

Description
gastrointestinal bleeding
Timepoint
10 days after doing ERCP
Method of measurement
Clinical observation

Intervention groups

1

Description
Intervention group: Administration of single dose of 100 mg rectal Indomethacine just before plus 200 mg CoQ10 tablet 2 hours before doing Endoscopic cholangiopancreatography
Category
Prevention

2

Description

Control group: Administration of single dose of 100 mg rectal indomethacine just before doing Endoscopic cholangiopancreatography

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

School of pharmacy, Shahid Behesti University of Medical Sciences

Full name of responsible person

Mohammad Abbasinazari

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8887 3704

Email

m_abbasi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Hassan Yazdanpanah

Street address

School of Pharmacy, Nyayesh junction, Valiasr street

City

Tehran

Province

Tehran

Postal code

1996835113

Phone

+98 21 8866 5282

Email

yazdanpanah@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Abbasinazari

Position

full professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

School of PharmacyNyayesh junction,Valiasr street

City

Tehran

Province

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1996835113

Phone

+98 21 8887 3704

Email

m_abbasi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Mohammad Abbasinazari

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Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Mohammad Abbasinazari

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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
Yes - There is 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 data can be shared after deidentified

When the data will become available and for how long
starting in July 2023

To whom data/document is available
only available for people working in academic institutions

Under which criteria data/document could be used
with written consent

From where data/document is obtainable
Sending email to: m_abbasi@sbmu.ac.ir

What processes are involved for a request to access data/document
Sending email to: m_abbasi@sbmu.ac.ir

Comments