

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of efficacy IV Ketorolac and Indomethacin to prevention post ERCP pancreatitis and hyperamylasemia in patients under going ERCP

Protocol summary

Study aim

Comparison of the efficacy intravenous ketorolac and indomethacin suppositories in the prevention of acute pancreatitis and hyperamylasemia after Endoscopic retrograde cholangiopancreatography

Design

This study was a randomized clinical trial designed for two parallel armies, double blind and single center. The study group is for all men and women 18 to 85 years of age who have an indication of Endoscopic retrograde cholangiopancreatography. Randomization is done using Win Pepi software. The number of samples in each group is 18 and in total 36 will be.

Settings and conduct

Patients are randomly entered into one of the two arms of the study, including the intervention arm and the control arm, and will be treated with indomethacin suppository or venous ketorolac. Post-Endoscopic retrograde cholangiopancreatography examinations are done at intervals of 2, 12, and 24 hours, including blood samples for serum amylase and lipase examination, examination of the patient in terms of abdominal pain, Visual Analog Scale, dose and dose of pethidine used, vital signs, nausea and vomiting is. Patients will be monitored for ketorolac and indomethacin for digestive and renal complications.

Participants/Inclusion and exclusion criteria

all men and women 18 to 85 years of age who have an indication of Endoscopic retrograde cholangiopancreatography. exclusion : Recent Acute pancreatitis and contraindication for the use of Nonsteroidal Anti Inflammatory Drugs

Intervention groups

the first group included treatment with riger lactate serum during Endoscopic retrograde cholangiopancreatography(ERCP)and 8 hours later with indomethacin suppository. In the other arm, In addition to standard hydration, 30 mg intravenous ketorolac is injected .

Main outcome variables

Age of sex,creatinine clearance, underlying diseases, Hyperamylasemia, Hyperlipazemy, Pethidine dose, Pancreatitis severity, Pain rate, Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190420043330N1**

Registration date: **2020-03-30, 1399/01/11**

Registration timing: **retrospective**

Last update: **2020-03-30, 1399/01/11**

Update count: **0**

Registration date

2020-03-30, 1399/01/11

Registrant information

Name

Navid Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4233 0086

Email address

n.hosseini@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-15, 1398/02/25

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy IV Ketorolac and Indomethacin to prevention post ERCP pancreatitis and hyperamylasemia in pateints under going ERCP

Public title

Effect of IV Ketorolac to prevention post ERCP pancreatitis

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Indication of ERCP

Exclusion criteria:**Age**

From **18 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Use Win Pepi

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients, nurse , supervisor and researcher don't know which group of patients will use the ketorolac or indomethacin . Physician and clinicians team know about the drug and group who use the drug.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Qazvin University of Medical

Sciences

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Dept of research Qazvin University of Medical Sciences Shahid Beheshti, Ave Qazvin' IRAN

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Province

Qazvin

Postal code

1391134156

Approval date

2019-05-12, 1398/02/22

Ethics committee reference number

IR.QUMS.REC.1398.030

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

post ERCP pancreatitis

ICD-10 code

K85

ICD-10 code description

Acute pancreatitis

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

rate of Acute Pancreatitis Post Ercp

Timepoint

At intervals 2, 12 and 24 hours after ERCP, blood samples are taken to check serum amylase and lipase.

Method of measurement

questionnaire

Secondary outcomes

empty

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

The standard treatment was ridge-ralcate serum hydration at a rate of 1.5cc / kg / h during ERCP and eight hours after receiving indomethacin suppository rectal immediately after ERCP.

Category

Treatment - Drugs

2**Description**

Intervention group: The standard treatment was hydrating with Ringer Lactate serum at 1.5cc / kg / h during ERCP and eight hours later, and 30 mg intravenous ketorolac immediately after ERCP.

Category

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vellayat hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Amir peymani

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Navid Hosseini

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact**

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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

No more 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available