Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of indomethacin suppository plus vitamin C injection verusus indomethacin suppository in prevention of post ERCP pancreatitis

Protocol summary

Study aim
Comparing the effect of single dose of rectal Indomethacin plus vitamin C injection versus single dose of rectal indomethacin on prevention of post ERCP pancreatitis

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
setting: Endoscopy ward of Talighani hospital, Tehran,Iran

Participants/Inclusion and exclusion criteria
Inclusion Criteria: During 1 year, all patients who undergo ERCP by taking consent inform will be enrolled in this study. Exclusion criteria: patients who will undergo a prior endoscopic sphincterotomy.

Intervention groups
Group1: Adminstration of single dose of 100 mg rectal indomethacine plus injection of 500 mg vitamin C just 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: **IRCT20121021011192N11**
Registration date: **2021-04-04, 1400/01/15**
Registration timing: **prospective**

Last update: **2021-04-04, 1400/01/15**
Update count: **0**

Registration date
2021-04-04, 1400/01/15

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
2021-05-21, 1400/02/31

Expected recruitment end date
2022-05-21, 1401/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of indomethacin suppository plus vitamin C injection verusus indomethacin suppository in prevention of post ERCP pancreatitis

Public title
Comparing the rectal Indomethacin plus vitamin C injection versus rectal indomethacin on prevention of post ERCP 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 vitamin C Active peptic ulcer diseases Renal impairment (GFR < 10 ml/min)

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

simple, block, individual, using table of random numbers.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

2021-03-13, 1399/12/23

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.375

Health conditions studied

1

Description of health condition studied

pancreatitis

ICD-10 code

K85.8

ICD-10 code description

Other acute pancreatitis

Primary outcomes

1

Description

pancreatitis

Timepoint

10 days after doing ERCP

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

Group1: Adminstration of single dose of 100 mg rectal indomethacine just before doing Endoscopic cholangiopancreatography Group2: Administration of single dose of 100 mg rectal Indomethacine plus 500 mg vitamin C injection 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
Tehran
Postal code
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
Full name of responsible person
Mohammad Abbasinazari
Position
full professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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

Person responsible for updating data

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 Pharmacy, Nyayesh junction, Valiasr street
City
Tehran
Province
Tehran
Postal code
1996835113
Phone
009888873704
Email
□_abbasi@sbmu.ac.ir

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 December 2021

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