

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparing the effect of single dose of rectal Indomethacin and oral Melatonin on prevention of post ERCP pancreatitis

Protocol summary

Study aim

Comparing the effect of single dose of rectal Indomethacin and oral Melatonin 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: Administration of single dose of 100 mg rectal indomethacin just before doing Endoscopic cholangiopancreatography Group2: Administration of single dose of 3 mg oral melatonin just before doing Endoscopic cholangiopancreatography

Main outcome variables

pancreatitis occurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121021011192N6**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

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

2017-08-24, 1396/06/02

Expected recruitment end date

2018-08-24, 1397/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of single dose of rectal Indomethacin and oral Melatonin on prevention of post ERCP pancreatitis

Public title

Comparing the effect of single dose of rectal Indomethacin and oral Melatonin 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 melatonin, indomethacin or diclofenac Active peptic ulcer diseases Renal impairment (GFR < 10 ml/min)

Age
 From **18 years** old to **70 years** old

Gender
 Both

Phase
 4

Groups that have been masked

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

Sample size
 Target sample size: **200**

Randomization (investigator's opinion)
 Randomized

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

Blinding (investigator's opinion)
 Double blinded

Blinding description
 participants, principle investigator, Physicians who care for participants, data collectors, outcome assessors

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Deputy of Reserch, School of Pharmacy, Shahid Beheshti University of Medical Scien

Street address

school of pharmacy,nyayesh junction, valiasr street

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

IR.SBMU.RAM.REC.1396.16

Health conditions studied

1

Description of health condition studied

pancreatitis

ICD-10 code

K85

ICD-10 code description

Acute pancreatitis

Primary outcomes

1

Description

Occurrence of pancreatitis

Timepoint

10 days after intervention

Method of measurement

Clinical evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Receiving indomethacin suppository 100 mg just before doing Endoscopic Retrograde Cholangiopancreatography and Intervention group 2: Receiving melatonin tablet 3 mg just before doing Endoscopic Retrograde Cholangiopancreatography

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Talighani hospital

Full name of responsible person

Mohammad Abbasinazari

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Arabi street, Velenjak

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1991967876

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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

Nima Naderi

Street address

تهران-خیابان ولی عصر-تقاطع نیایش-دانشکده داروسازی

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Grant name

Grant code / Reference number

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

No

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

nima naderi

Position

En Vice chancellor for research, Shahid Beheshti University of Medical

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

School of pharmacy, Shahid Beheshti University of Medical Science

Full name of responsible person

Mohammad-Abbasinazari

Position

ph.D in clinical pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Email

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Person responsible for updating data

Contact

Name of organization / entity

School of pharmacy, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrnaz Rasoulinezhad

Position

Pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Others

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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

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

Undecided - It is not yet known if there will be 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 March 2019

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

With

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