Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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: Adminstration of single dose of 100 mg rectal indomethacine just before doing Endoscopic cholangiopancreatography Group2: Administration of single dose of 3 m oral melatonin just before doing Endoscopic cholangiopancreatography
Main outcome variables
pancreatitis occurence

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 consen

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

Street address
Arabi street, Velenjak

City
Tehran

Province
Tehran

Postal code
1991967876

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
Nima Naderi
Street address
تهران-خیابان ولی عصر-تقاطع نیایش-دانشکده داروسازی
City
Tehran
Province
Tehran
Postal code
0098218887370400
Phone
+98 21 8887 3704
Email
m_abbasi@sbmu.ac.ir
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
Street address
school of pharmacy,nyayesh junction, valiasr street
City
tehran
Province
Tehran
Postal code
00982188873704
Phone
00
Email
naderi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of pharmacy, Shahid Beheshty 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
Street address
school of pharmacy,nyayesh junction, valiasr street
City
tehran
Province
Tehran
Postal code
00982188873704
Phone
00
Email
m_abbasi@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
School of pharmacy, Shahid Beheshty University of Medical Sciencese
Full name of responsible person
Mehrnaz Rasoulinezhad
Position
Pharmacist
Latest degree
Medical doctor
Other areas of specialty/work
Others
Street address
School of pharmacy, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8887 3704
Email
m_abbasi@sbmu.ac.ir

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