Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of ERCP complications with Diclofenac suppository and Acetaminophen suppository patients with CBD stone

Protocol summary

Summary
Objectives: Determine the effects of ERCP complications in patients receiving Diclofenac suppository with patients receiving acetaminophen suppositories in patients with gallstones Design: Randomized, Not-blind. The main inclusion criteria to study: the need for ERCP (Endoscopic Retrograde Cholangiopancreatography) due to gallstones. The main exclusion criteria from study: presence of coagulation disorders have already been diagnosed; Taking medications that may interfere with coagulation tests. Intervention group: Diclofenac Suppository, Before ERCP Control group: Acetaminophen Suppositories, Before ERCP Primary outcome measure: Bleeding rate, During ERCP and during 24 hours after ERCP, By monitoring vital signs and clinical examination

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2014020616504N1**
Registration date: **2014-03-02, 1392/12/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2014-03-02, 1392/12/11

Registrant information
Name
Hadi Bagheri Hosseini
Name of organization / entity
Imam Reza Hospital
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Recruitment status
Recruitment complete
Funding source
Vice Chancellor for Research of Mashhad University of Medical Sciences

Expected recruitment start date
2014-01-11, 1392/10/21
Expected recruitment end date
2014-10-13, 1393/07/21
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of ERCP complications with Diclofenac suppository and Acetaminophen suppository patients with CBD stone

Public title
Determine the effects of ERCP complications in patients receiving diclofenac suppository with patients receiving acetaminophen suppositories in patients with gallstones
Purpose
Diagnostic
Inclusion/Exclusion criteria
The main inclusion criteria to study: the need for ERCP (Endoscopic Retrograde Cholangiopancreatography) due to gallstones. The main exclusion criteria from study: presence of coagulation disorders have already been diagnosed; Taking medications that may interfere with coagulation tests.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
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 Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research of Mashhad University of Medical Sciences, Ghoreishi Building, Daneshgah Street, Mashhad
City
Mashhad
Postal code
Approval date
2014-01-11, 1392/10/21
Ethics committee reference number
911196

Health conditions studied

1

Description of health condition studied
Nonsteroidal anti-inflammatory drugs
ICD-10 code
Y45.3
ICD-10 code description
Other nonsteroidal anti-inflammatory drugs

Primary outcomes

1

Description
Bleeding rate
Timepoint
During ERCP and during 24 hours after ERCP
Method of measurement
Monitoring vital signs and clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diclofenac Suppository, Once before ERCP
Category
Treatment - Drugs

2

Description
Control group: Acetaminophen Suppositories, Once before ERCP
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Hadi Bagheri Hosseini
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Imam Reza Hospital, Imam Reza Square, Mashhad
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Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

Vice Chancellor for Research of Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty