

# Pharmacological Prophylaxis of Post- Endoscopic Retrograde Cholangiopancreatography (ERCP) Pancreatitis

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. [Know the risks and potential benefits](#) of clinical studies and talk to your health care provider before participating. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier:  
NCT03708458

Recruitment Status :  
Recruiting  
First Posted : October 17, 2018  
Last Update Posted :  
October 18, 2018  
See [Contacts and Locations](#)

**Sponsor:**

Grigore T. Popa University of Medicine and Pharmacy

**Information provided by (Responsible Party):**

PAVEL LAURA, Grigore T. Popa University of Medicine and Pharmacy

- Study Details

Tabular View

No Results Posted

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[How to Read a Study Record](#)

Study Description

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Brief Summary:






The investigators aimed to perform a comparative study, evaluating the efficacy of three prophylactic approaches aiming to reduce the risk of post-ERCP pancreatitis, using pharmacologic agents with different mechanisms of action (NSAIDs and/or acetylcysteine) in three different regimens.

<a href="#">Condition or disease</a>	<a href="#">Intervention/treatment</a>	<a href="#">Phase</a>
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Post-ERCP Pancreatitis	Drug: indomethacin suppository Drug: N-acetylcysteine (NAC)	Phase 4
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## Study Design

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<a href="#">Study Type</a> 	Interventional (Clinical Trial)
Estimated <a href="#">Enrollment</a> 	250 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Prevention
Official Title:	Comparative Evaluation of Standard Prophylaxis Versus Divided-dose NSAIDs or Hybrid NSAID and N-acetylcysteine Therapy for the Prevention of Post-ERCP Pancreatitis
Actual <a href="#">Study Start Date</a> 	April 1, 2017
Estimated <a href="#">Primary Completion Date</a> 	December 15, 2018
Estimated <a href="#">Study Completion Date</a> 	December 15, 2018

### Resource links provided by the National Library of Medicine



[Genetics Home Reference](#) related topics:

[Hereditary pancreatitis](#)



[MedlinePlus](#) related topics: [Pancreatitis](#)

[Drug Information](#) available for: [Indomethacin](#)  
[Acetylcysteine](#)

[U.S. FDA Resources](#)

## Arms and Interventions

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<a href="#">Arm</a> 	<a href="#">Intervention/treatment</a> 
Active Comparator: Control group Control group - patients receiving 100 mg indomethacin suppository immediately post ERCP	Drug: indomethacin suppository the investigators aimed to perform a comparative study, evaluating the efficacy of three prophylactic approaches aiming to reduce the risk of PEP, using

	indomethacin and/or N-acetylcysteine -NAC, in different regimens
Active Comparator: Group A  Group A - patients receiving N-acetylcysteine (NAC) 600 mg before performing ERCP and indomethacin suppository 50 mg before and after performing ERCP	Drug: indomethacin suppository  the investigators aimed to perform a comparative study, evaluating the efficacy of three prophylactic approaches aiming to reduce the risk of PEP, using indomethacin and/or N-acetylcysteine -NAC, in different regimens  Drug: N-acetylcysteine (NAC)  the investigators aimed to perform a comparative study, evaluating the efficacy of three prophylactic approaches aiming to reduce the risk of PEP, using indomethacin and/or N-acetylcysteine -NAC, in different regimens
Active Comparator: Group B  Group B - patients receiving indomethacin suppository 50 mg before and 50 mg after ERCP	Drug: indomethacin suppository  the investigators aimed to perform a comparative study, evaluating the efficacy of three prophylactic approaches aiming to reduce the risk of PEP, using indomethacin and/or N-acetylcysteine -NAC, in different regimens

Outcome Measures

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Primary Outcome Measures  :

1. Number of patients who develop post ERCP pancreatitis [ Time Frame: 24 hours post ERCP ]
- Comparing and evaluating the efficacy of three pharmacological combination therapies (Indomethacin +/- N-acetylcysteine), aiming to prevent acute post ERCP pancreatitis

Eligibility Criteria

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*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).*

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

## Criteria

### Inclusion Criteria:

- age 18 years and older
- diagnosis of choledocholithiasis
- indication for ERCP procedures
- willingness to participate in the study
- the ability to sign the informed consent

### Exclusion Criteria:

- presence of acute pancreatitis or other inflammatory diseases at admission
- pregnancy
- contraindication for NSAID administration
- recent episode of upper digestive bleeding (less than one month)
- hypersensitivity to antioxidants hypersensitivity to antioxidants
- the necessity of a prophylactic pancreatic stent insertion
- patients' disapproval to take part in the study

## Contacts and Locations

Go to 

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):

**NCT03708458**

## Contacts

Contact: LAURA PAVEL, PhD Student +40751129600 [laura\\_pavel\\_88@yahoo.com](mailto:laura_pavel_88@yahoo.com)

Contact: GABRIELA STEFANESCU, PhD, Lecturer +40744244266 [gabriela.stefanescu@gmail.com](mailto:gabriela.stefanescu@gmail.com)

## Locations

### Romania

Institute of Gastroenterology and Hepatology - St. Spiridon County Clinical Emergency Hospital  
Iasi, Romania, cod 700111

Contact: GHEORGHE BALAN, PROFESSOR +40732402845 [drbalanumfiasi@yahoo.com](mailto:drbalanumfiasi@yahoo.com)

## Sponsors and Collaborators

Grigore T. Popa University of Medicine and Pharmacy

## Investigators

Study Director: GHEORGHE BALAN, PhD, Professor "GRIGORE T. POPA" UNIVERSITY OF MEDICINE AND PHARMACY

## More Information

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## Publications:

[Dumonceau JM, Andriulli A, Elmunzer BJ, Mariani A, Meister T, Deviere J, Marek T, Baron TH, Hassan C, Testoni PA, Kapral C; European Society of Gastrointestinal Endoscopy. Prophylaxis of post-ERCP pancreatitis: European Society of Gastrointestinal Endoscopy \(ESGE\) Guideline - updated June 2014. Endoscopy. 2014 Sep;46\(9\):799-815. doi: 10.1055/s-0034-1377875. Epub 2014 Aug 22.](#)

[Yaghoobi M, Rolland S, Waschke KA, McNabb-Baltar J, Martel M, Bijarchi R, Szego P, Barkun AN. Meta-analysis: rectal indomethacin for the prevention of post-ERCP pancreatitis. Aliment Pharmacol Ther. 2013 Nov;38\(9\):995-1001. doi: 10.1111/apt.12488. Epub 2013 Sep 16.](#)

[Levenick JM, Gordon SR, Fadden LL, Levy LC, Rockacy MJ, Hyder SM, Lacy BE, Bensen SP, Parr DD, Gardner TB. Rectal Indomethacin Does Not Prevent Post-ERCP Pancreatitis in Consecutive Patients. Gastroenterology. 2016 Apr;150\(4\):911-7; quiz e19. doi: 10.1053/j.gastro.2015.12.040. Epub 2016 Jan 9.](#)

[Gooshe M, Abdolghaffari AH, Nikfar S, Mahdavian P, Abdollahi M. Antioxidant therapy in acute,](#)

[chronic and post-endoscopic retrograde cholangiopancreatography pancreatitis: An updated systematic review and meta-analysis. World J Gastroenterol. 2015 Aug 14;21\(30\):9189-208. doi: 10.3748/wjg.v21.i30.9189. Review.](#)

[Fuentes-Orozco C, Dávalos-Cobián C, García-Correa J, Ambriz-González G, Macías-Amezcu MD, García-Rentería J, Rendón-Félix J, Chávez-Tostado M, Cuesta-Márquez LA, Alvarez-Villaseñor AS, Cortés-Flores AO, González-Ojeda A. Antioxidant drugs to prevent post-endoscopic retrograde cholangiopancreatography pancreatitis: What does evidence suggest? World J Gastroenterol. 2015 Jun 7;21\(21\):6745-53. doi: 10.3748/wjg.v21.i21.6745. Review.](#)

[Katsinelos P, Kountouras J, Paroutoglou G, Beltsis A, Mimidis K, Zavos C. Intravenous N-acetylcysteine does not prevent post-ERCP pancreatitis. Gastrointest Endosc. 2005 Jul;62\(1\):105-11.](#)

[Elmunzer BJ, Scheiman JM, Lehman GA, Chak A, Mosler P, Higgins PD, Hayward RA, Romagnuolo J, Elta GH, Sherman S, Waljee AK, Repaka A, Atkinson MR, Cote GA, Kwon RS, McHenry L, Piraka CR, Wamsteker EJ, Watkins JL, Korsnes SJ, Schmidt SE, Turner SM, Nicholson S, Fogel EL; U.S. Cooperative for Outcomes Research in Endoscopy \(USCORE\). A randomized trial of rectal indomethacin to prevent post-ERCP pancreatitis. N Engl J Med. 2012 Apr 12;366\(15\):1414-22. doi: 10.1056/NEJMoa1111103.](#)

[Luo H, Zhao L, Leung J, Zhang R, Liu Z, Wang X, Wang B, Nie Z, Lei T, Li X, Zhou W, Zhang L, Wang Q, Li M, Zhou Y, Liu Q, Sun H, Wang Z, Liang S, Guo X, Tao Q, Wu K, Pan Y, Guo X, Fan D. Routine pre-procedural rectal indometacin versus selective post-procedural rectal indometacin to prevent pancreatitis in patients undergoing endoscopic retrograde cholangiopancreatography: a multicentre, single-blinded, randomised controlled trial. Lancet. 2016 Jun 4;387\(10035\):2293-2301. doi: 10.1016/S0140-6736\(16\)30310-5. Epub 2016 Apr 28.](#)

Responsible Party:	PAVEL LAURA, Principal Investigator, PhD Student, Grigore T. Popa University of Medicine and Pharmacy
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Last Update Posted:	October 18, 2018
Last Verified:	October 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by PAVEL LAURA, Grigore T. Popa University of Medicine and Pharmacy:  
endoscopic retrograde  
cholangiopancreatography (ERCP)  
post-ERCP pancreatitis (PEP)  
Nonsteroidal anti-inflammatory drugs (NSAID's)  
acetylcysteine (ACC)

Additional relevant MeSH terms:

Pancreatitis	Protective Agents
Pancreatic Diseases	Physiological Effects of Drugs
Digestive System Diseases	Antidotes
Acetylcysteine	Analgesics, Non-Narcotic
N-monoacetylcystine	Analgesics
Indomethacin	Sensory System Agents
Anti-Inflammatory Agents, Non-Steroidal	Peripheral Nervous System Agents
Antiviral Agents	Anti-Inflammatory Agents
Anti-Infective Agents	Antirheumatic Agents
Expectorants	Gout Suppressants
Respiratory System Agents	Tocolytic Agents
Free Radical Scavengers	Reproductive Control Agents
Antioxidants	Cyclooxygenase Inhibitors
Molecular Mechanisms of Pharmacological Action	Enzyme Inhibitors