

## 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](#)

[Disclaimer](#)

 [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.

[Condition or disease](#) 

[Intervention/treatment](#) 

[Phase](#) 

Post-ERCP Pancreatitis	Drug: indomethacin suppository Drug: N-acetylcysteine (NAC)	Phase 4
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## Study Design

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[Study Type](#) **i** : Interventional (Clinical Trial)  
[Estimated Enrollment](#) **i** : 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 Study Start Date](#) **i** : April 1, 2017  
[Estimated Primary Completion Date](#) **i** : December 15, 2018  
[Estimated Study Completion Date](#) **i** : 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> <b>i</b>	<a href="#">Intervention/treatment</a> <b>i</b>
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
<p>Active Comparator: Group A</p> <p>Group A - patients receiving N-acetylcysteine (NAC) 600 mg before performing ERCP and indomethacin suppository 50 mg before and after performing ERCP</p>	<p>Drug: indomethacin suppository</p> <p>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</p> <p>Drug: N-acetylcysteine (NAC)</p> <p>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</p>
<p>Active Comparator: Group B</p> <p>Group B - patients receiving indomethacin suppository 50 mg before and 50 mg after ERCP</p>	<p>Drug: indomethacin suppository</p> <p>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</p>

## 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

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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, Iași, 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  
ClinicalTrials.gov Identifier: [NCT03708458](#) [History of Changes](#)  
Other Study ID Numbers: PEP\_2017  
First Posted: October 17, 2018 [Key Record Dates](#)  
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

Pancreatic Diseases

Digestive System Diseases

Acetylcysteine

N-monoacetylcystine

Indomethacin

Anti-Inflammatory Agents, Non-Steroidal

Antiviral Agents

Anti-Infective Agents

Expectorants

Respiratory System Agents

Free Radical Scavengers

Antioxidants

Molecular Mechanisms of Pharmacological  
Action

Protective Agents

Physiological Effects of Drugs

Antidotes

Analgesics, Non-Narcotic

Analgesics

Sensory System Agents

Peripheral Nervous System Agents

Anti-Inflammatory Agents

Antirheumatic Agents

Gout Suppressants

Tocolytic Agents

Reproductive Control Agents

Cyclooxygenase Inhibitors

Enzyme Inhibitors