

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The comparison of efficacy of oral oral N-acetylcysteine (NAC) with rectal indomethacin in prevention of post ERCP pancreatitis

Protocol summary

Study aim

The comparison of efficacy of oral oral N-acetylcysteine (NAC) with rectal indomethacin in prevention of pancreatitis after ERCP

Design

This is a multicenter clinical trial study with parallel groups, double-blinded randomized, will be conducted on 280 patients undergoing ERCP. Assignment of patients to the study groups will be done by random-numbers table and using computer.

Settings and conduct

This multicenter study will be performed on patients undergoing ERCP in Imam Khomeini and Golestan hospitals, Ahvaz. At least 280 patients will be randomly assigned to one of four treatment groups. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who candidate for endoscopic retrograde cholangiopancreatography (ERCP), including patients with jaundice due to biliary obstruction; imaging findings indicating pancreatic duct obstruction; consent to participate in the study. Exclusion criteria: history of pancreatitis before ERCP; uncontrolled diabetes; triglyceride more than 1000 mg/dL.

Intervention groups

In first group, N-acetylcysteine 1200 mg (Osvah Pharmaceutical Company, Iran Exir CO., Iran) is drunk with 150 cc water two hours before endoscopic retrograde cholangiopancreatography (ERCP) (the appearance of the drug after dissolving in water is colorless and has no difference with control group). In the second group, 150 cc water is given as a placebo before ERCP. In the third group, patients will receive 100 mg rectal indomethacin (Abureihan Company, Iran) before ERCP. In the fourth group, oral acetylcysteine (1200 mg) with rectal indomethacin (100 mg) are given before ERCP.

Main outcome variables

Incidence of pancreatitis; severity of pancreatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201222049798N1**

Registration date: **2020-12-29, 1399/10/09**

Registration timing: **prospective**

Last update: **2020-12-29, 1399/10/09**

Update count: **0**

Registration date

2020-12-29, 1399/10/09

Registrant information

Name

Ali akbar Abravesh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3222 2922

Email address

abravesh.aa@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of efficacy of oral oral N-acetylcysteine (NAC) with rectal indomethacin in prevention of post ERCP pancreatitis

Public title

Efficacy of oral NAC and rectal indomethacin in prevention pancreatitis after ERCP

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who candidate for endoscopic retrograde cholangiopancreatography (ERCP) including patients with jaundice due to biliary obstruction and imaging findings indicating pancreatic duct obstruction Consent to participate in the study

Exclusion criteria:

History of pancreatitis before ERCP Uncontrolled diabetes, Triglyceride more than 1000 mg/dL

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned into four groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the four treatment groups before starting ERCP. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Intervention (receiving oral N-acetylcysteine, rectal indomethacin, N-acetylcysteine with rectal indomethacin or water) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Also patients and statistical analyzer will not know about patient grouping.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2020-12-08, 1399/09/18

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1399.120

Health conditions studied**1****Description of health condition studied**

Pancreatitis

ICD-10 code

K85.9

ICD-10 code description

Acute pancreatitis, unspecified

Primary outcomes**1****Description**

Incidence of pancreatitis

Timepoint

24 hours after ERCP

Method of measurement

Based on the amount of amylase increase (more than 276 IU/di) and the presence of abdominal pain and patient report of abdominal pain after ERCP

2**Description**

Severity of pancreatitis

Timepoint

Duration of hospitalization

Method of measurement

Based on the number of hospitalization days (mild pancreatitis: hospitalization less than 4 days, moderate pancreatitis: 4 to 10 days; severe pancreatitis: more than 10 days)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: N-acetylcysteine 1200 mg (Osvah Pharmaceutical Company, Iran Exir CO., Iran) is drunk with 150 cc water two hours before endoscopic retrograde cholangiopancreatography (ERCP) (the appearance of the drug after dissolving in water is colorless and has no difference with control group).

Category

Prevention

2

Description

Control group: 150 cc water is given as a placebo before ERCP

Category

Prevention

3

Description

Intervention group: patients will receive 100 mg rectal indomethacin (Abureihan Company, Iran) before ERCP.

Category

Prevention

4

Description

Intervention group: oral acetylcysteine (1200 mg) with rectal indomethacin (100 mg) are given before ERCP.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ali Akbar Abravesh

Street address

Imam Khomeini Hospital, Azadegan St.

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2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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badavim@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali akbar Abravesh

Position

Adult gastroenterology fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available