

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

EVALUATION OF N ACETYL CYCTEIN IN PREVENTION OF POST ERCP PANCREITIS: A DOUBLE BLIND randomized PILOT STUDY

Protocol summary

Summary

Acute pancreatitis is the most common serious complication of ERCP which occasionally could be fatal. Multiple drugs have been examined for prevention of this side effect with generally uncertain results. This study is an effort for prevention of this complication with using oral N acetyl Cysteine. Materials and Methods: Overall 100 patients who were candidate for ERCP divided randomly to two groups. In the group N, 1200 mg N Acetyl Cysteine with 150cc water prescribed orally 2 hours before ERCP and in group P, 150cc water prescribed as placebo. Serum Amylase and Lipase have measured before and 24 hours after ERCP and prevalence of pancreatitis and duration of admission in each group were determined and compared together.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008094545N1**

Registration date: **2012-12-23, 1391/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-23, 1391/10/03

Registrant information

Name

Pezhman Alavi nejad

Name of organization / entity

Ahvaz Jondishapur University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1391 2533

Email address

ehajiani@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz jondi shapur medical university

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EVALUATION OF N ACETYL CYCTEIN IN PREVENTION OF POST ERCP PANCREITIS: A DOUBLE BLIND randomized PILOT STUDY

Public title

Evaluation of NAC for prevention of post ERCP pancreatitis: a prospective double blind randomized pilot study

Purpose

Prevention

Inclusion/Exclusion criteria

every patient candidate for ERCP in GI ward of Ahwaz Imam hospital except those with preexisting pancreatitis or uncontrolled diabetes melitus

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

research center of ahwaz jondi shapur univercity

Street address

department of reaserch and technology, medical univercity, shahid chamran univercity

City

ahwaz

Postal code

Approval date

2011-05-21, 1390/02/31

Ethics committee reference number

ETH-272

Health conditions studied

1

Description of health condition studied

post ERCP pancreatitis

ICD-10 code

K85.8

ICD-10 code description

other acute pancreatitis

Primary outcomes

1

Description

serum lipase

Timepoint

before and after ERCP

Method of measurement

level of enzyme in serum

2

Description

serum amylase

Timepoint

before and 24 hours after ERCP

Method of measurement

measurement of enzyme level in serum

Secondary outcomes

1

Description

incidence of pancreatitis

Timepoint

24 hours after ERCP

Method of measurement

enzyme level in serum

2

Description

abdominal pain

Timepoint

after ERCP

Method of measurement

to be or not to be

3

Description

duration of addmision

Timepoint

how long

Method of measurement

how many days

Intervention groups

1

Description

NAC 1200mg in 150 cc water

Category

Prevention

2

Description

150cc water

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

GI department of Ahwaz Imam Hospital

Full name of responsible person

Dr Pezhman Alavi nejad

Street address

GI department, Imam Hospital, azadegan street

City
Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jondi Shapur medical univercity

Full name of responsible person

Dr Homeira Rashidi

Street address

research center department of medical univercity

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahwaz Jondi Shapur medical univercity

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

Name of organization / entity

AhwazJdi Shapur medical univercity

Full name of responsible person

Dr Pezhman Alavi nejad

Position

fellow ship of gastroenterology

Other areas of specialty/work

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Contact

Name of organization / entity

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Full name of responsible person

Dr PEZHMAL ALAVI NEJAD

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Person responsible for updating data

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Name of organization / entity

MEDICAL UNIVERCITY

Full name of responsible person

Dr PAZHMAL ALAVI NEJAD

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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