

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of aggressive Hydration versus nonsteroidal anti-inflammatory drug therapy in prevention of post Endoscopic Retrograde Cholangiopancreatogram pancreatitis: a double blind randomized clinical trial

Protocol summary

Summary

This study was designed to evaluate the effect of aggressive Hydration versus NSAID (nonsteroidal anti-inflammatory drug) therapy in prevention of post ERCP (Endoscopic Retrograde Cholangiopancreatogram) pancreatitis. A double blind randomized controlled clinical trial study including 186 patients will be conducted on three groups of hospitalized patients (n=62) undergoing ERCP procedure in gastrointestinal ward at Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. Patients and evaluating physician are blinded regarding type of intervention. Patients will be randomly assigned to the group of study using random list. Inclusion criteria are ERCP for biliary stones or stenting insertion. Exclusion criteria are acute cholangitis, Sepsis, chronic pancreatitis, acute pancreatitis caused by gallstones, patients undergoing balloon dilatation of papilla, patients at risk due to increased fluid volume, heart diseases, pregnant women, history of pancreatitis after ERCP, patients who had pancreatic stent. The first group will receive the solution ringer lactate bolus 20 cc/kg then 3 cc/kg/h after ERCP procedure (n=62) and the second group will receive one indomethacin rectally every 12 hours for 24 hours (n=62) and the third group will receive placebo (n=62) after ERCP. To confirm the diagnosis of pancreatitis, every 8 and 24 hours after intervention the abdominal pain and amylase level will be assessed. In the case of abdominal pain and amylase level over 270 IU/dl the pancreatitis will be confirmed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070323026N1**

Registration date: **2015-07-31, 1394/05/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-31, 1394/05/09

Registrant information

Name

Nima AghaMohammadi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3221 6504

Email address

aghamohammadi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-01-01, 1393/10/11

Expected recruitment end date

2016-01-01, 1394/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aggressive Hydration versus nonsteroidal

anti-inflammatory drug therapy in prevention of post Endoscopic Retrograde Cholangiopancreatogram pancreatitis: a double blind randomized clinical trial

Public title

The effect of aggressive Hydration in prevention of pancreatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: hospitalized patients who underwent Endoscopic Retrograde Cholangiopancreatography (ERCP) Exclusion criteria: acute cholangitis; sepsis; chronic pancreatitis; acute pancreatitis due to gallstones; patients at risk of increasing fluid volume; pregnant women; patient undergoing papilla dilatation; history of pancreatitis after ERCP; patients with stent embedded in pancreatic duct.

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 186

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

Ethics committee in research of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan blvd., Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City

Ahvaz

Postal code

Approval date

2014-12-30, 1393/10/09

Ethics committee reference number

ajums.REC.1393.403

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

Pancreatitis

Timepoint

8 hours and 24 hours after ERCP procedure

Method of measurement

Abdominal pain plus amylase level over 270 IU/dl

Secondary outcomes

empty

Intervention groups

1

Description

Group 1: Solution ringer lactate bolus 20 cc/kg then 3 cc/kg/h for 8 hours.

Category

Treatment - Drugs

2

Description

Group 2: Indomethacin rectally every 12 hours for 24 hours

Category

Treatment - Drugs

3

Description

Group 3: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Zeinab Shajirat

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Abdolrahim Masjedizadeh

Street address

Imam Khomeini hospital, Ahvaz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur 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

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

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Web page address

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