Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 conducted on three groups of hospitalized patients (n=62) undergoing ERCP procedure in gastrointesitinal 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 randomly assigned to the group of study using random list. Inclusion criterion is 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 cholongitis; 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

Ahvaz

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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Zeinab Shajirat
Position
Master of science
Other areas of specialty/work
Street address
Imam Khomeini Hospital Ahvaz
City
Ahvaz
Postal code
Phone
+98 936 491 6479
Fax
Email
zeinab.shajirat@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Zeinab Shajirat
Position
Master of Science
Other areas of specialty/work
Street address
Imam Khomeini Hospital, Ahvaz
City
Ahvaz
Postal code
Phone
+98 936 491 6479
Fax
Email
zeinab.shajirat@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Zeinab Shajirat
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
zeinab.shajirat@gmail.com
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