Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The effect of aggressive hydration with Lactated Ringer’s solution during and post endoscopic retrograde cholangiopancreatography(ERCP) in prevention of post-ERCP pancreatitis (PEP)

Protocol summary

Study aim

-Investigating the effect of hydration with a high dose of Ringer's lactate during and after retrograde endoscopic cholangiography(ERCP) on the prevention of post ERCP pancreatitis(PEP); Helping to prevent the occurrence of PEP and its negative consequences

Design

Clinical trial with a control group, double-blinded, randomized, on 150 patients

Settings and conduct

Eligible patients are randomly divided into 2 groups. Blinding is done in such a way that the person who will randomize people to groups, the endoscopist, the patients, the person who evaluates the results, and the person who analyzes the results do not know any information about the grouping and random assignment of patients in the study groups.

Participants/Inclusion and exclusion criteria

Eligibility criteria: ERCP candidate patients who are 18 to 75 years old, patients undergoing ERCP for the first time Exclusion criteria: age over 75 years, presence of concurrent acute pancreatitis, history of gastrectomy, history of severe cardiovascular, liver, kidney and respiratory diseases or electrolyte disorders

Intervention groups

The first group recieve aggressive hydration with Ringer's lactate solution 10 ml/kg of the initial bolus before the ERCP, 3 ml/kg/hr during the ERCP and for 8 hours after ERCP and a bolus of 10 ml per kilogram after ERCP. The second group receive standard hydration with Ringer's lactate solution 1.5 ml/kg/hr during and for 8 hours after procedure.

Main outcome variables

The primary end point of the study was the development of post-ERCP pancreatitis؛ and the secondary end point was severity of pancreatitis, hyperamylasemia, and fluid overload.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221228056959N1**
Registration date: **2022-12-31, 1401/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-31, 1401/10/10**
Update count: **0**

Registration date

2022-12-31, 1401/10/10

Registrant information

Name

Hamidreza Zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 190 8779

Email address

hamidreza.zarei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of aggressive hydration with Lactated Ringer's solution during and post endoscopic retrograde cholangiopancreatography(ERCP) in prevention of post-ERCP pancreatitis (PEP)

Public title
The effect of aggressive hydration with Lactated Ringer's solution during and post endoscopic retrograde cholangiopancreatography(ERCP) in prevention of post-ERCP pancreatitis (PEP)

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who urdergo ERCP for the first time Age 18 to 75 years Patient consent to participate in the study

Exclusion criteria:
Age over 75 years Concomitant acute pancreatitis History of gastrectomy surgery (Billroth II surgery) or reconstruction with Roux-en-Y method History of severe cardiovascular, liver, kidney and respiratory diseases or electrolyte disorders: class II heart failure based on NYHA criteria, recent myocardial ischemia (in the past three months); Cirrhosis of the liver; Renal failure with increased creatinine clearance < 40 mL/min; chronic obstructive pulmonary disease (COPD) requiring oxygen (oxygen saturation < 90%); Hypernatremia (serum sodium > 150 mEq/L) or hyponatremia (serum sodium < 130 mEq/L)

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
The way of randomization is that people are divided into two groups with equal numbers using random blocks created by the Random allocation software, by a person who is not involved in the study process.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is done in such a way that the person who will perform the randomization and allocation of people to groups, the endoscopist, the patients, the person who evaluates the results, and the person who analyzes the results have no information about the grouping and randomization of patients in the study groups. the study is done in a double-blind manner. An independent specialist doctor who is not involved in this research administers the fluids.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Golestan Hospital

Street address
Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2022-12-13, 1401/09/22

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.157

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
Amylase

Timepoint
Measurement of serum amylase at the beginning and at 2, 8 and 24 hours after ERCP

Method of measurement
Serum amylase measurement laboratory kit

2

Description
Epigastric pain

Timepoint
For 24 hours after ERCP

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Severity of pancreatitis
Timepoint
Examination of the patient in terms of the severity of pancreatitis every eight hours up to 48 hours
Method of measurement
Atlanta classification

2

Description
Volume overload
Timepoint
Once every eight hours up to 48 hours
Method of measurement
Lung auscultation

3

Description
Bleedind
Timepoint
Once every eight hours up to 48 hours
Method of measurement
Hematemesis or melena in examination and hemoglobin drop in laboratory tests

4

Description
Pleural effusion
Timepoint
Up to 48 hours after ERCP
Method of measurement
Chest X-Ray

Intervention groups

1

Description
Intervention group: The intervention group recieve aggressive hydration with Ringer's lactate solution 10ml/kg initial bolus before surgery, 3ml/kg/h during ERCP procedure and for 8 hours after procedure, and a post procedure bolus of 10ml/kg.
Category
Prevention

2

Description
Control group: The control group received standard hydration with Ringer's lactate solution 1.5 mL/kg/h for 8 hours during and after ERCP.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeyni hospital of Ahvaz
Full name of responsible person
Hamidreza Zarei
Street address
Azadegan Blvd, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 2922
Email
hemam@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehrnoush Zakerkish
Street address
Depatment of Research and Technology, Ahvaz University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir
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
Hamidreza Zarei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Imam Khomini hospital, Azadegan st.
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 2922
Email
hamidreza.zarei@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Jalal Sayyah
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Imam Khomeyni, Azadegan st, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 2922
Email
sayah-j@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Hamidreza Zarei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Imam Khomini hospital, Azadegan st.
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 2922
Email
hamidreza.zarei@yahoo.com

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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
Data on the main outcome and side effects can be shared after de-identification of participants.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data will be accessible for scientific and practical use by researchers of academic institutions.
From where data/document is obtainable
Applicants to receive documents or data can contact Hamidreza Zarei through the following: Phone: 0098 9171908779 Email: hamidreza.zarei@yahoo.com
What processes are involved for a request to access data/document
There is no further information.
Comments