Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of efficacy & safety of aggressive hydration therapy with ringer’s lactated solution on pancreatitis after endoscopic retrograde cholangiopancreatography (ERCP) in patient candidate for ERCP

Protocol summary

Study aim

The purpose of this study is investigating the effect of aggressive hydration with lactate ringer in preventing acute pancreatitis after Endoscopic retrograde cholangiopancreatography

Design

Study is carried out in a single blind randomized, clinical trial on 164 patients up to 70 year’s old, and candidate Endoscopic retrograde cholangiopancreatography. Patients will be divided into two control and intervention groups by simple random method (closed packet method)

Settings and conduct

Study is carried out in a single blind, one centric clinical trial at Velayat hospital in Qazvin. Patients do not know about the assignment of study groups.

Participants/Inclusion and exclusion criteria

Major Inclusion criteria: Indication of endoscopic retrograde cholangiopancreaticography; consent of enrollment in study. Exclusion criteria: Acute cholangitis; sepsis; pregnancy; chronic pancreatitis; acute pancreatitis due to billiary stone; risk of fluid overload; peripheral edema

Intervention groups

Interventions: Intervention Group: In the case group, Ringer's lactate solution with 20 cc/Kg was administered bolus and then with a dose of 3 cc/Kg during 8 hours after ERCP and in the control group Ringer's lactate solution is given at a dose of 1.5 cc / kg during 8 hours after ERCP. Receiving intravenous fluid in both groups will be interrupted when they are able to eat a normal diet.

Main outcome variables

Main outcome variable: Acute pancreatitis (abdominal pain, serum amylase and lipase) will be assessed at 6, 12 and 24 hours after Intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171009036664N1**
Registration date: **2018-01-11, 1396/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-11, 1396/10/21**
Update count: **0**

Registration date

2018-01-11, 1396/10/21

Registrant information

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Ali Bastani
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-31, 1396/10/10

Expected recruitment end date

2018-07-01, 1397/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of efficacy & safety of aggressive hydration therapy with ringer’s lactated solution on pancreatitis after endoscopic retrograde cholangiopancreatography (ERCP) in patient candidate for ERCP

Public title
Evaluation & safety of lactated ringer’s solution on prevention of acute pancreatitis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Indication for endoscopic retrograde cholangiopancreaticography (ERCP); Consent of enrollment in the study
Exclusion criteria:
Acute cholangitis; Sepsis; Pregnancy; Age above 70 years; Chronic pancreatitis; Acute pancreatitis due to billiary stone; evidence of fluid overload; Peripheral edema; Pulmonary edema; Electrolyte disturbance for example Na over 150 or below 130; Cirrhosis Renal failure History of endoscopic retrograde cholangiopancreaticography performation with sphinctrotomy
Age
To **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **164**
Randomization (investigator's opinion)
Randomized
Randomization description
simple random method (sealed packet method)
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants will be blinded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Qazvin University of Medical Sciences
Street address
Shahid Bahonar Blvd, Qazvin
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2017-02-11, 1395/11/23
Ethics committee reference number
IR.QUMS.REC.1395.268

Health conditions studied

1

Description of health condition studied
Acute pancreatitis
ICD-10 code
K85
ICD-10 code description
Acute pancreatitis

Primary outcomes

1

Description
Post endoscopicretrograde cholangiopancreatography pancreatitis
Timepoint
6, 12 and 24 hours after endoscopicretrograde cholangiopancreatography procedure
Method of measurement
Clinical examination (abdominal pain) & laboratory testing(amylase, and/or lipase levels to ≥3 times the upper limit of normal)

Secondary outcomes

1

Description
Complications of ERCP
Timepoint
6, 12 and 24 hours after endoscopicretrograde cholangiopancreatography procedure
Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention group: serum lactate ringer with 20 cc/Kg was administered bolus and then with a dose of 3 cc/Kg to 8 hours after ERCP

Category
Prevention

2

Description
Control group: Serum lactate ringer is given at a dose of 1.5 cc / kg up to 8 hours after ERCP.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat educational and treatment center
Full name of responsible person
Mahnaz Abbasi
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
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Person responsible for updating data

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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
No - There is not a plan to make this available
Data Dictionary
Not applicable