Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

TO compare intense hydration and fluid standard therapy before and after of ERCP in the prevention of post ERCP pancreatitis

Protocol summary

Study aim
To compare intense hydration and fluid standard therapy before and after of ERCP in the prevention of post ERCP pancreatitis

Design
In this study, 160 patients have been assigned to two groups of intervention and control by using random numbers table.

Settings and conduct
In this clinical trial, all patients who undergo ERCP in Ayatollah Rouhani Hospital with diagnosis of common bile duct stone (uncomplicated) diagnosis include the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria includes all patients over 18 years who were referred to hospital for ERCP. Patients disorders in liver function tests or had extrahepatic cholestasis. Exclusion criteria include history of PEP and Pancreatitis with Other Pancreatic Risk Factors and Diseases, Heart Failure, IBD, NSAID Allergy, Coagulation Disorders, Chronic renal failure Current hypotension (eg septic shock), Severe liver failure, Respiratory failure, Pregnancy, Hyponatremia or Hypnothermia, Edema or ascites, Using high-risk outside the stone during the ERCP procedure.

Intervention groups
One group was treated with ringer lactat serum and another group with Standard fluid therapy.

Main outcome variables
Pancreatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191226045897N1**
Registration date: **2020-02-22, 1398/12/03**
Registration timing: **retrospective**
Last update: **2020-02-22, 1398/12/03**
Update count: **0**

Registration date
2020-02-22, 1398/12/03

Registrant information

Name
Seyed Hassan Abedi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-01, 1397/02/11

Expected recruitment end date
2019-05-01, 1398/02/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
TO compare intense hydration and fluid standard therapy before and after of ERCP in the prevention of post ERCP pancreatitis

Public title
Compare intense hydration and fluid standard therapy before and after of ERCP in the prevention of post ERCP pancreatitis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients over 18 years who were referred to hospital for ERCP. Patients disorders in liver function tests or had extrahepatic cholestasis.

Exclusion criteria:

History of PEP and Pancreatitis with Other Pancreatic Risk Factors and Diseases Heart Failure IBD NSAID Allergy Coagulation Disorders Chronic renal failure Current hypotension (eg septic shock) Severe liver failure Respiratory failure Pregnancy Hyponatremia or Hypnothermia Edema or ascites Using high-risk outside the stone during the ERCP procedure

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

These patients were randomly divided into two groups of 80 aggressive fluid therapy before and after ERCP and standard fluid therapy before and after ERCP.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City

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Province

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Postal code

4716681451

Approval date

2018-05-01, 1397/02/11

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.179

Health conditions studied

1

Description of health condition studied

Acute Pancreatitis

ICD-10 code

k85.8

ICD-10 code description

Other Acute Pancreatitis

Primary outcomes

1

Description

Pancreatitis

Timepoint

24 hours after ERCP

Method of measurement

Amylase serum, Patient's symptoms(nausea, vomiting and abdominal pain)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ringer's lactate serum was infused at a rate 1.5 times the standard limit of 4.5 cc / h before ERCP (approximately 3200 cc over 12 h with a mean weight of 60 kg) and at and after this rate. will continue.

Category

Prevention

2

Description

Control group: During and after the liquid ERCP second group received standard treatment (/ 5CC / kg / hr1 to 12 hours later).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Ayatollah Rouhani Hospital

Full name of responsible person

Dr. sayed Hassan abedi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Babol 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
Babol University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
-
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available