Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparing Short-term effects of aggressive hydration therapy with lactated Ringer’s solution before cholangiopancreatography for prevention of complications compared with not using of serum before the Endoscopic retrograde cholangiopancreatography

Protocol summary

Summary

This study aims at evaluating the effect of short-aggressive fluid therapy with Ringer solution before ERCP (Endoscopic Retrograde cholangiopancreatography) on the prevention of pancreatitis related to ERCP. 240 samples were evaluates. An inclusion criterion of the study was the indication for endoscopy, etc. Exclusion criteria: Active cholangitis; Age over 70 years; Chronic pancreatitis, etc. A total of 240 samples were estimated that 120 people will be randomly assigned to two groups. For the intervention group, aggressive fluid therapy, a dose of 20 ml / kg of Ringer lactate within 90 minutes before endoscopy And 3 ml/ kg /h is given during ERCP with 3 to 8 mL / kg /h will continue. If there is no pain, it will become 1.5 ml / kg /h. For the control group, 1.5 mL / kg /h during ERCP are Ringer lactate which will continue up to 8 hours after ERCP. For Both groups who received intravenous fluid when they are able to eat a normal diet, it will be cut. Then all patients by way of ERCP (guide wire), will be treated. Upon completion of ERCP, all patients 2, 8 and 24 hours later will be visited by the digestive flow. Review of fluids through clinical examinations will be at or ankle edema, pulmonary crackles, or decreased O2 Saturation. In addition to pancreatitis, two criteria are forming pancreatitis (Hyperamylasemia and Pain) as studied variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608101213N4**
Registration date: **2016-09-18, 1395/06/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-09-18, 1395/06/28

Registrant information

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Manouchehr Khoshbaten
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research -Tabriz University of Medical Science

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Short-term effects of aggressive hydration therapy with lactated Ringer’s solution before cholangiopancreatography for prevention of complications compared with not using of serum before

the Endoscopic retrograde cholangiopancreatography

Public title
The impact of aggressive hydration therapy with lactated Ringer’s solution before procedure on outcomes after Endoscopic Retrograde CholangioPancreatography
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Indication of endoscopic retrograde cholangiopancreatography; Consent of enrollment in study and Exclusion criteria:Acute cholangitis; Sepsis; Pregnancy; Age above 70 years; Chronic pancreatitis; Acute pancreatitis due to biliary stone; Risk of fluid overload; Peripheral edema; Pulmonary edema; Electrolyte disturbance for example Na over 150 or below 130; History of endoscopic retrograde cholangiopancreatography per formation with sphincterotomy.
Age
To **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Central bulding of medical science university, St. Golgasht, St. Azadi ,Tabriz Tabriz
City
Tabriz
Postal code
Approval date
2016-07-12, 1395/04/22
Ethics committee reference number
IR.TBZMED.REC.1395.289

Health conditions studied

1

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

Primary outcomes

1

Description
Post endoscopicretrograde cholangiopancreatography pancreatitis
Timepoint
2,8 and 24 hours after intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Hyper amylasemia
Timepoint
2,8 and 24 hours after intervention
Method of measurement
U/L

2

Description
Pain
Timepoint
2,8 and 24 hours after intervention
Method of measurement
Visual analouge pain scale

Intervention groups

1

Description
For the intervention group, aggressive fluid therapy, a dose of 20 ml / kgof Ringer lactate within 90 minutes before endoscopy And 3 mL / kg /h is given during ERCP with 3 to 8 mL / kg /h will continue.If there is no pain, it will become 5.1 ml / kg /h.
Category
Treatment - Drugs

2

Description

For the control group, 1.5 mL / kg /h during ERCP is Ringer lactate which will continue up to 8 hours after ERCP.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz, Tabriz University of Medical Sciences, Imam Reza Hospital

Full name of responsible person

Dr.Ramin Ghaderi

Street address

Endoscopy ward, first floor, Imam Reza Hospital, St. Golgasht, St.Azadi, Tabriz, East Azarbaijan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Vice chancellor for Research of Tabriz University of Medical Sciences,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Manouchehr Khoshbaten

Position

Gastroentrology and hepatology/ Professor

Other areas of specialty/work

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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