

# 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 evaluated. 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

###### Name

Manouchehr Khoshbaten

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1334 7554

###### Email address

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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

**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. Goltasht, St. Azadi ,Tabriz Tabriz

**City**

Tabriz

**Postal code**

**Approval date**

2016-07-12, 1395/04/22

**Ethics committee reference number**

**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**

Gastroentology and hepatology/ Professor

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**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*