Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of short term protective effect of aggressive hydration therapy with lactated ringer’s solution on pancreatitis after endoscopic retrograde cholangiopancreatography

Protocol summary

Summary

150 patient candidate for endoscopic retrograde cholangiopancreatography in 5 months period with inclusion criteria(Choledochobilliary Stone; Dilatation and Obstraction of Choledochobilliary) and without exclusion criteria(Acute Cholangitis; Pregnancy; End Organ Failure; Age above 70 years) divided to two groups, case and control randomizely.That's obvious for researcher exclusively. For case group aggressive hydration and for control group routine hydration therapy will be done. Both groups discontinue intravenous fluids when they are able to eat a normal diet.The aim of this study is evalution of aggressive hydration therapy in prevention of post endoscopic retrograde cholangiopancreatography pancreatitis as primary end point.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410161213N3**
Registration date: **2014-10-19, 1393/07/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-10-19, 1393/07/27

Registrant information

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Manouchehr Khoshbaten

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research -Tabriz University of Medical Science

Expected recruitment start date

2014-11-06, 1393/08/15

Expected recruitment end date

2015-04-20, 1394/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of short term protective effect of aggressive hydration therapy with lactated ringer’s solution on pancreatitis after endoscopic retrograde cholangiopancreatography

Public title

Effect of aggressive hydration therapy in prevention of complication of endoscopic theraputic intervention on billiary duct.

Purpose

Prevention

Inclusion/Exclusion criteria

(Inclusion criteria:Indication of endoscopic retrograde cholangiopancreaticography; consent of enrollment in study and Exclusion criteria:Acute cholangitis; sepsis; pregnancy; age above 70 years; chronic pancreatitis; acute pancreatitis due to billiary stone; risk of fluid

overload; peripheral edema; pulmonary edema; electrolyte disturbance for example Na over 150 or below 130; history of endoscopic retrograde cholangiopancreaticography performation with sphinctrotomy.)

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: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences , affiliated to the Ministry of Health, Treatment and Medical

Street address
Central bulding of medical science university, St. Golgasht, St. Azadi ,Tabriz

City
Tabriz

Postal code

Approval date
2014-10-12, 1393/07/20

Ethics committee reference number
93104

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 cholangiopancreaticography pancreatitis

Timepoint
2,8 and 24 hours after intervation

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Hyper amylasemia

Timepoint
2, 8 and 24 after intervation

Method of measurement
U/L

2

Description
Pain

Timepoint
2, 8 and 24 after intervation

Method of measurement
Visual analouge pain scale

Intervention groups

1

Description
In case group lactated ringer serum administer with dose of 20 cc per kilogram of body mass and continue with 3 cc per kilogram of body mass until 8 hours.

Category
Treatment - Drugs

2

Description
In control group lactated ringer serum administer with dose of 1.5 cc per kilogram of body mass until 8 hours.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences

Full name of responsible person
Ali reza shayegan nezhad

Street address
Endoscopy ward, first floor, Imam Reza Hospital, St.

Golgasht, St.Azadi
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research -Tabriz University of Medical Science
Full name of responsible person
Dr.Mohammad Reza Rashidi
Street address
Third floor, Central building No.2, Tabriz University of Medical Sciences ,St.Golgasht
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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 -Tabriz University of Medical Science
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
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Person responsible for updating data

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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