# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

21 Jul 2026

## Evaluation effect of intravenous Hydrocortisone on hyperamylasemia of patients underwent Endoscopic retrograde cholangiopancreatography

## Protocol summary

**Summary**

The aim of this clinical trial was evaluation effect of intravenous hydrocortisone on hyperamylasemia of patients underwent Endoscopic retrograde cholangiopancreatography (ERCP). Inclusion criteria included highness of amylase levels (less than three times normal) before ERCP. Exclusion criteria included current or history of corticosteroid use within 2 weeks ago, developing pancreatitis during the 2 weeks before ERCP and developing chronic pancreatitis. This study that performed on patients underwent ERCP. 90 patients evaluated in two case and control groups, in case group, Ampoule hydrocortisone (manufactured by pharmaceutical Exir) 100 mg will inject intravenously slowly at 0.5-1 hours before ERCP. In control group, 2 cc Normal saline (Placebo) will injected at 0.5-1 hours before ERCP. Amylase levels of patients will be checked at 2 hours after ERCP.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201410236388N6**
Registration date: **2014-12-19, 1393/09/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2014-12-19, 1393/09/28

**Registrant information**

**Name**

Mohamadhossein Somi

**Name of organization / entity**

Tabriz University of Medical Science

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 1336 7499

**Email address**

somimh@tbzmed.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor of Tabriz University of Medical Sciences

**Expected recruitment start date**

2013-12-22, 1392/10/01

**Expected recruitment end date**

2014-11-22, 1393/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation effect of intravenous Hydrocortisone on hyperamylasemia of patients underwent Endoscopic retrograde cholangiopancreatography

**Public title**

Evaluation effect of Hydrocortisone on amylase level of patients underwent Endoscopic retrograde cholangiopancreatography

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria:Highness of Amylase levels (less than three times normal) before ERCP. Exclusion criteria: Developing diabetes; Current or history of corticosteroid use within 2 weeks ago; Developing pancreatitis during the 2 weeks before ERCP; Developing chronic pancreatitis

**Age**

No age limit

**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **90**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Tabriz University of Medical Sciences
**Street address**
Medical Faculty, Tabriz University of Medical Sciences, Daneshghah Ave, Tabriz
**City**
Tabriz
**Postal code**
**Approval date**
2010-04-28, 1389/02/08
**Ethics committee reference number**
9318

## Health conditions studied

**1**

**Description of health condition studied**
Acute pancreatitis
**ICD-10 code**
K85.9
**ICD-10 code description**
Disease of pancreas, unspecified

## Primary outcomes

**1**

**Description**
Serum Amylase
**Timepoint**
2 hours after ERCP
**Method of measurement**
Check by Laboratory

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Case Group: injection Ampoule hydrocortisone (manufactured by pharmaceutical Exir) 100 mg intravenously at 0.5-1 hours before ERCP
**Category**
Treatment - Drugs

**2**

**Description**
Control Group: Injection of 2 cc Normal saline (Placebo) at 0.5-1 hours before ERCP
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Tabriz Imam Reza Hospita
**Full name of responsible person**
**Street address**
**City**
Tabriz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor of Tabriz University of Medical Sciences
**Full name of responsible person**
Mrs. Azari
**Street address**
Tabriz University of Medical Sciences
**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 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. Amin Sadrazar

**Position**

Resident of Internal Medicine

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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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*