Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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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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