

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

copmarsion of treatment effects with and without the use of Fluconazole on acute biliary pancreatitis

Protocol summary

Summary

The aim of this study is to evaluate the therapeutic effect of fluconazole on acute biliary pancreatitis. The desired number of samples, 76 patients with acute biliary pancreatitis admitted to Imam Reza Hospital are selected and they are divided into two groups through Table of random numbers. In one group the routine treatment is performed (included Restriction of oral intake, correction of water and electrolyte, pain management, intravenous fluids and monitoring of central venous pressure, urine output controls the prescription of prophylactic antibiotics) and in other group, Fluconazole is added to the treatment regimen. Agreement form is completed for all patients and Patients are not aware of being in the fluconazole group or standard treatment. Inclusion criteria: consists of those who have been diagnosed with acute biliary pancreatitis based on clinical; laboratory and ultrasound results. criteria excluded: Pregnant women; patients with a history of previous hypersensitivity to fluconazole to mention; person that any allergies or suffer from the study. The severity of disease in patients is determined based on Ransom criteria on admission or CT Scan. Mild cases are cared in general ward and severe cases are hospitalized or admitted in the intensive care unit. Ransom criteria and serum amylase levels will be recalculated at 48 h after admission. Patients in both groups are evaluated in terms of complications, requiring to necrosectomy surgery, hospital stay duration, staying in the intensive care unit and cost of hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082714333N3**

Registration date: **2013-09-23, 1392/07/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-23, 1392/07/01

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

copmarsion of treatment effects with and without the use of Fluconazole on acute biliary pancreatitis

Public title

Evaluation of Fluconazole treatment effects on acute biliary pancreatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients consists of those who have been diagnosed with acute biliary pancreatitis based on clinical; laboratory and ultrasound results. criteria excluded: Pregnant women; patients with a history of previous hypersensitivity to fluconazole to mention; person that any allergies or suffer from the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 76

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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2013-05-18, 1392/02/28

Ethics committee reference number

7206/7/420/پ

Health conditions studied

1

Description of health condition studied

biliary acute pancreatitis

ICD-10 code

k85.1

ICD-10 code description

biliary acute pancreatitis

Primary outcomes

1

Description

Severity of disease

Timepoint

at starting point and six months later

Method of measurement

Based on Ratson criteria and CT. Scan

2

Description

necessity to operation

Timepoint

at starting point and 6 months later

Method of measurement

based on patient records

3

Description

duration of staying in hospita

Timepoint

at starting point and 6 months later

Method of measurement

based on patient records

4

Description

duration of staying in hospital

Timepoint

at starting point and 6 months later

Method of measurement

based on patient records

5

Description

costs of disease

Timepoint

at starting point and 6 months later

Method of measurement

based on patient records

6

Description

treatments

Timepoint

at starting point and 6 months later

Method of measurement

based on patient records

7

Description

complications

Timepoint

at starting point and 6 months later

Method of measurement

based on patient records

8

Description

mortality rate

Timepoint

at starting point and 6 months later

Method of measurement

based on patient records

Secondary outcomes

empty

Intervention groups

1

Description

routine treatment (included Restriction of oral intake, correction of water and electrolyte, pain management intravenous fluids and, monitoring of central venous pressure, urine output controls the prescription of prophylactic antibiotics) to control group

Category

Treatment - Drugs

2

Description

Fluconazole is added to the treatment regimen for five days in the intervention group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Dr. Farhang Safarnejad

Street address

Dep.surgery,Emam Reza Hospital,Razi
Boulevard,Sorkhleje

City

Kermanshah

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for
Research Affairs, Kermanshah University of Medical
Sciences

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Seyed Mohamad Ali Hesami

Position

thorasic surgeon

Other areas of specialty/work**Street address**

Dep.surgery,Emam Reza Hospital,Razi
Boulevard,Sorkhleje

City

Kermanshah

Postal code**Phone**

+98 931 427 6308

Fax**Email**

mahessami@hotmail.com

Web page address**Person responsible for updating data****Contact****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