Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

efficacy of Diclofenac suppository on treatment of acute biliary pancreatitis

Protocol summary

Study aim

Determination of the Effect of Diclofenac Suppository on the Therapy of Acute Biliary Pancreatitis

Design

Clinical trial with a control group and parallel group trial and double blinded. The sample size is 80 people with simple randomization

Settings and conduct

This is a clinical trial study that will be carried out at Kowsar Hospital in Sanandaj. After dividing the groups, in the case group, diclofenac suppository 100 mg every 8 hours will give to the patient until the day before the operation , and in the control group placebo suppository is given to the patient. Other treatments are similar for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Acute pancreatitis, which in its definition should be There are at least two criteria of the three following criteria: a) pain in the upper abdomen, b) serum amylase or lipase> 3 times normal, or c) acute pancreatitis imaging features in CT or MRI . 2) A biliary cause based on the minimum of the following conditions: A. Biliary stone or biliary sludge in imaging (any type) B) A dilated common bile duct in the imaging that is> 8 mm in Patients ≤ 75 years or> 10 mm in patients> 75 years of age C) Alanine aminotransferase more than twice as normal. 3) informed consent of the patient. 4) Age more than 18 years Non-compliance criteria: 1) Cholangitis 2) Pancreatitis for other causes such as alcohol abuse, metabolic causes (hyperthermia or hypercalcemia), medication, trauma, etc. 3) Chronic pancreatitis 4) Pregnancy

Intervention groups

In the intervention group, patients get diclofenac suppository 100 mg every 8 hours until the day before surgery. in the control group, placebo suppository will be added to the treatment with same condition in the case group

Main outcome variables

death Organ failure Necrotizing pancreatitis Cholangitis (Cholangitis in the course of treatment) The need for surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181028041485N1**
Registration date: **2019-02-12, 1397/11/23**
Registration timing: **retrospective**

Last update: **2019-02-12, 1397/11/23**
Update count: **0**

Registration date

2019-02-12, 1397/11/23

Registrant information

Name

Morteza Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4648

Email address

yousefi.m@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-03-20, 1395/12/30

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

2018-04-08, 1397/01/19

Scientific title

efficacy of Diclofenac suppository on treatment of acute biliary pancreatitis

Public title

efficacy of diclofenac on pancreatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute pancreatitis, which in its definition should have at least two criteria of the following three criteria: a) pain in the upper abdomen, b) serum amylase or lipase> 3 times of normal, orc) acute pancreatitis features In computer tomography (CT) or magnetic resonance imaging (MRI) A biliary cause based on at least one of the following conditions: a) gallstone or sludge in the imaging (any type); b) common bile duct > 8 mm in patients <75 years of age or> 10 mm in patients> 75 years of age. C) Alanine aminotransferase (AST) more than twice as normal; Conscious informed consent; Age older than 18 years.

Exclusion criteria:

Cholangitis Pancreatitis for other causes such as alcohol abuse, metabolic causes (hyperthermia or hypercalcemia), medication, trauma, etc. Chronic pancreatitis Pregnancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization was Simple randomization. In this way, we divided the patients who had the inclusion criteria, into two groups with a closed envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who will be present in the study will take a Suppository an will be supplemented by nurses based on which group they will be in, and the patient will not know what Suppository are given to him/her. In the case of the statistical advisor in the same way, only the data will be analyzed between the two groups and statistical advisor will not be known which group get the placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Kowsar hospital, Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6616894581

Approval date

2017-05-01, 1396/02/11

Ethics committee reference number

IR.MUK.REC.1396/212

Health conditions studied

1

Description of health condition studied

Pancratitis

ICD-10 code

K85.1

ICD-10 code description

Biliary acute pancreatitis

Primary outcomes

1

Description

Mortality

Timepoint

End of the research

Method of measurement

Number of people

2

Description

Organ failure

Timepoint

End of the research

Method of measurement

Lab test & physical exam

3

Description
Necrotizing pancratitis
Timepoint
End of the research
Method of measurement
Abdominal & pelvic CT scan

4

Description
Bacteremia
Timepoint
During the study
Method of measurement
Lab test

5

Description
Cholangitis
Timepoint
During the study
Method of measurement
Lab test & physical exam

6

Description
Need for necrozectomy surgery
Timepoint
During the study
Method of measurement
Abdominal & pelvic CT scan

7

Description
Number of ICU & hospital admissions days
Timepoint
End of the research
Method of measurement
Number of days

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Diclofenac Suppository 100 mg every 8 hours will be added until symptom improvement and the day before surgery.
Category
Treatment - Drugs

2

Description
Control group: Placebo Suppository every 8 hours will be added until the day before surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar hospital
Full name of responsible person
Farhang Safarnezhad
Street address
Kowsar hospital, Pasdaran Blvd
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6616894581
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+98 87 3361 1306
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Yousefi.M@muk.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Farzin Razaei
Street address
Deputy of research and technology, kurdistan University of medical scince, Pasdaran Blvd
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6616894231
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+98 87 3366 4645
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Yousefi.M@Muk.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Morteza Yousefi

Position
Rezident of general surgery

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All collected data is shareable and has no limitations

When the data will become available and for how long
The access period will be available after printing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
There is no limitation

From where data/document is obtainable
Deputy of Research of Kurdistan University of Medical Sciences

What processes are involved for a request to access data/document
The data are visible after request from the deputy of research and after confirmation of the request within one month

Comments