

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment the role of somatostatin and indomethacin versus only indomethacin in the incidence of post - ERCP pancreatitis

Protocol summary

Study aim

Evaluation of the effect of injectable somatostatin with indomethacin on the incidence of pancreatitis after endoscopic retrograde cholangiography compared with indomethacin and placebo

Design

In this clinical trial, all patients with diagnosis of bile duct disorders who referred to perform ERCP method in 5 Azar hospital. Comparison between two study groups will be done in terms of age and sex of the patient and the reason for performing ERCP. Necessary ethical licenses will be obtained from the ethics committee of Golestan University of Medical Sciences. A written informed consent will be obtained from all. Patients will then be randomly divided into two groups: 1) injectable somatostatin and indomethacin, and 2) indomethacin and placebo. Serum amylase levels are considered to be more than 3 times normal as hyper-amylase.

Settings and conduct

This study will be performed as a randomized, triple-blind, clinical trial in Gorgan's 5 Azar Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with biliary tract disorders refer to Gorgan 5 Azar Hospital to perform ERCP from the beginning of March 2018. Exclusion criteria: previous sphincterotomy, history of chronic pancreatitis. Allergy to somatostatin or NSAIDS

Intervention groups

Group 1: somatostatin plus indomethacin
Group 2: Indomethacin plus placebo

Main outcome variables

Age, gender, ERCP reason, pancreatitis, treatment type, amylase level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080921001264N11**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **retrospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Sima Besharat

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 17 1224 4170

Email address

besharat@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-03-20, 1397/12/29

Scientific title

Assessment the role of somatostatin and indomethacin versus only indomethacin in the incidence of post - ERCP pancreatitis

Public title

Role of somatostatin in the incidence of post - ERCP pancreatitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with biliary tract problems who refer to 5 Azar Hospital in Gorgan to perform ERCP diagnostic-therapeutic method from the beginning of April 2017.

Exclusion criteria:

Previous history of sphincterotomy history of chronic pancreatitis acute pancreatitis when visiting Allergy to somatostatin or NSAIDs

Age

From **18 years** old to **95 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **360**

Actual sample size reached: **376**

Randomization (investigator's opinion)

Randomized

Randomization description

In this way, using the Block Balanced Randomization method with four blocks and preparing a list of blocks and assigning numbers to them, a list of treatment allocations is prepared and patients are assigned to one of the somatostatin and indomethacin groups or indomethacin group according to the list

Blinding (investigator's opinion)

Triple blinded

Blinding description

Due to the use of numbers to randomly assign patients to treatment groups and the use of quadruple blocks, all patients are coded. Patients in the intervention group and patients in the control and subspecialty group of gastroenterologists performing ERCP, the laboratory assessing the level of amylase, and the statistical consultant analyzing the data will be unaware of which group the patient belongs to. Evaluation and increase of accuracy and objectivity of clinical results were performed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Golestan University of Medical Sciences

Street address

Shast kola

City

Gorgan

Province

Golestan

Postal code

4918936316

Approval date

2018-06-17, 1397/03/27

Ethics committee reference number

IR.GOUMS.REC.1397.042

Health conditions studied

1

Description of health condition studied

Pancreatitis

ICD-10 code

K85.9

ICD-10 code description

Acute pancreatitis, unspecified

Primary outcomes

1

Description

Pancreatitis

Timepoint

2 and 18 hours

Method of measurement

serum amylase

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: somatostatin plus indometacin. Somatostatin 250 µg bolus for 1-2 minutes pre-ERCP Long-term infusion of somatostatin 500µg, started during ERCP and lasted for two hours Indomethacin suppository 100mg pre-ERCP and 100mg post-ERCP

Category

Treatment - Drugs

2

Description

Control group: Indomethacin alone. For control group, normal saline and indomethacine suppository (100 mg) were administrated before and after ERCP.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar hospital

Full name of responsible person

Alireza Norouzi

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4918936316

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+98 17 3242 4103

Email

norouzi54@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

MohamadReza Honarvar

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

Yes

Title of funding source

Gorgan University of Medical Sciences

Proportion provided by this source

100

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

Gorgan University of Medical Sciences

Full name of responsible person

Alireza Norouzi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Alireza Norouzi

Position

MD, Gastroenterologist

Latest degree

Subspecialist

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after people have not been identified

When the data will become available and for how long

from December 2020

To whom data/document is available

all

Under which criteria data/document could be used

-

From where data/document is obtainable

To the PI of the study

What processes are involved for a request to access data/document

research deputy

Comments