Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intravenous somatostatin on prevention of pancreatitis after ERCP (Endoscopic Retrograde Cholangio-Pancreatography) in comparison with control group

Protocol summary

Study aim

Determination and comparison of PEP(post-ERCP Pancreatitis) incidence in patients receiving prophylactic intravenous bolus somatostatin plus rectal diclofenac versus placebo plus rectal diclofenac.

Design

Clinical trial with intervention and control groups, double blind, randomized, phase three. Randomization: Random block A, B. Randomization Unit: Individual. Randomization tool: random number table. The operating physician, assistant and patient will not be aware of any syringe content. Sample size: 50 patients in control group and 50 patients in intervention group.

Settings and conduct

Participants will be randomly divided into two groups of patients and controls. The operating physician, assistant, and patient will not be aware of any needle syringes (double blind). Randomly block A, B, individual randomization unit, table randomization tool. The drug syringe contains 250 micrograms of somatostatin and the placebo syringe contains distilled water. The endoscopy unit of Firoozgar Hospital will be located in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years ; Ability to sign consent ; Intact papillae ; No contraindication for somatostatin and diclofenac ; Having an ERCP indication ; Non-inclusion: Sphincterotomy ; Acute pancreatitis ; Basic amylase above 200 ; Allergy to somatostatin and diclofenac ;

Intervention groups

Intervention group: intravenous injection of 250 µg Somatostatin Control group: drug injection (distilled water)

Main outcome variables

Acute pancreatitis after ERCP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191231045969N1**
Registration date: **2020-02-18, 1398/11/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-18, 1398/11/29**
Update count: **0**

Registration date

2020-02-18, 1398/11/29

Registrant information

Name

Mehdi Nikkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1711

Email address

nikkhah.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-27, 1397/06/05

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of intravenous somatostatin on prevention of pancreatitis after ERCP (Endoscopic Retrograde Cholangio-Pancreatography) in comparison with control group

Public title
The effect of intravenous somatostatin on prevention of pancreatitis after ERCP (Endoscopic Retrograde Cholangio-Pancreatography)

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Ability to sign consent Intact papillae No contraindication for somatostatin and diclofenac Having an ERCP indication

Exclusion criteria:
Sphincterotomy Acute pancreatitis Basic amylase above 200 Allergy to somatostatin and diclofenac

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Method: Block A, B is random. Patients will be placed in pre-arranged charts in which A, B are listed, respectively, at the time of study, thereby prescribing for block A, the syringe containing the drug, and for block B, the syringe containing the drug. The operating physician, assistant, and patient will not be aware of any syringe content and the syringe code will be written to the file (double blind). Randomization Unit: Individual Randomization Tool: Table

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will be randomly assigned to block A and B randomly with the table randomization tool. The syringe code will be written to the file. The operating physician, assistant and patient will not be aware of any syringe content. (Double blind).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, next to Milad Tower, Hemat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2018-08-26, 1397/06/04

Ethics committee reference number
IR.IUMS.REC.1397.290

Health conditions studied

1

Description of health condition studied
Acute pancreatitis

ICD-10 code
K85

ICD-10 code description
Acute pancreatitis

Primary outcomes

1

Description
Acute pancreatitis after ERCP

Timepoint
24 hours after ERCP operation

Method of measurement
Examination and testing of lipase amylase

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Intravenous (distilled water) injection, 5cc intravenous injection, a syringe (no content and only one code insert) given to physician assistant to slow it for 1 to 2 minutes simultaneously Injections for the patient. The name of the distilled water company is SUPA and its chemical compound is H2O.

Category
Placebo

2

Description
Intervention group: Intravenous injection of 250 µg somatostatin (250 µg somatostatin dissolved in 5 ml distilled water), a syringe (without mentioning content and with only one code insert) given to the physician assistant slowly Inject 1 to 2 minutes with the cannulation for the patient. The manufacturer's name is somatostatin consumable, Eumedica.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Mehdi Nikkha
Street address
Firoozgar Hospital, Beh Afarin Street, Vali Asr Square
City
Tehran
Province
Tehran
Postal code
1593748711
Phone
+98 21 8893 7383
Fax
+98 21 8893 7383
Email
nikkhah.m@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Abbas Motevalian
Street address
Iran University of Medical Sciences, next to Milad Tower, Hemat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2504
Email
amotevalian@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mehdi Nikkhah
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Firoozgar Hospital, Beh Afarin Street, Vali Asr Square
City
Tehran
Province
Tehran
Postal code
1593748711
Phone
+98 21 8893 7383
Email
Nikkhah.m@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mehdi Nikkhah
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Firoozgar Hospital, Beh Afarin Street, Vali Asr Square
City
Tehran
Province
Tehran

Postal code
1593748711
Phone
+98 21 8893 7383
Email
nikkhah.m@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mehdi Nikkhah
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Firoozgar Hospital, Beh Afarin Street, Vali Asr Square
City
Tehran
Province
Tehran
Postal code
1593748711
Phone
+98 21 8893 7383
Email
Nikkhah.m@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available