# 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

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**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
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Firoozgar Hospital, Beh Afarin Street, Vali Asr Square
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## Sponsors / Funding sources

**1**

**Sponsor**
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**Full name of responsible person**
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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**
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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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