Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of "immediate" endoscopic necrosectomy vs. "on-demand" necrosectomy for treatment of infected walled-off pancreatic necrosis

Protocol summary

Study aim
Comparing the success rate of “immediate” vs. “on demand” endoscopic necrosectomy for infected walled off pancreatic necrosis (WOPN)

Design
Two arm, parallel group, single blind randomized clinical trial (randomization with using "random number table")

Settings and conduct
Patients with infected walled off pancreatic necrosis, admitted to the Shariati Hospital, Tehran, Iran, are randomly assigned to study groups. Patients at both groups would be followed up for 3 months and compared in terms of success rate and complications. The responsible physician for postprocedure care and the outcome assessors would be blinded to the random allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age at least 18 years 2. Definite diagnosis of infected walled off pancreatic necrosis 3. At least 20% solid component at the necrotic lesion Exclusion criteria: 1. Uncorrectable coagulopathy with platelet count less than 50,000 or international normalized ratio (INR) above 1.5 2. Location of the infected walled-off pancreatic necrosis is unreachable with endosonography 3. Pregnancy (in females) 4. Prior intervention on the infected walled-off pancreatic necrosis (such as cutaneous drainage, ...)

Intervention groups
"Immediate" necrosectomy group: Patients at this group will have endoscopic necrosectomy at the time of stent placement. "On demand" necrosectomy group: For patients in this group, endoscopic necrosectomy is not performed at the time of stent placement. Such patients may undergo endoscopic necrosectomy during follow up if clinically indicated.

Main outcome variables
Clinical success rate; Complication rate; Duration of hospitalization; Number of necrosectomy sessions; Mean time of necrosectomies; Size of walled off pancreatic necrosis after 1 and 3 months; Survival after 3 months; Incidence rate of new diabetes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220718055486N1**
Registration date: **2022-08-08, 1401/05/17**
Registration timing: **prospective**

Last update: **2022-08-08, 1401/05/17**
Update count: **0**

Registration date
2022-08-08, 1401/05/17

Registrant information

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Morteza Hassanzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of "immediate" endoscopic necrosectomy vs. "on-demand" necrosectomy for treatment of infected walled-off pancreatic necrosis

Public title
Endoscopic necrosectomy for treatment of infected walled-off pancreatic necrosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definite diagnosis of walled-off pancreatic necrosis At least 20% solid component at the necrotic lesion

Exclusion criteria:
Uncorrectable coagulopathy with platelet count < 50,000 or INR > 1.5 Location of the infected walled-off pancreatic necrosis is unreachable with endosonography Pregnancy (in females) Prior intervention on the infected walled-off pancreatic necrosis (such as cutaneous drainage, ...)

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Considering the small sample size and in order to balance the number of patients in two study groups, participants of this study were randomly assigned to each group using the restricted randomization method of "permuted block randomization". This way, in this study the block size of 4 would be used so that in each block 2 patients is assigned to the case group and 2 to the control one; having filled each block, the filling process of next block would be started. Before beginning of the investigation, the order of 10 blocks and the order of intra-block case assignment are prepared by a blinded statistician using “Random Allocation Software”, and the assignment would be performed accordingly as follows. The sequential blocks are saved in the computer as ten folders (numbered 1 to 10) each containing four Word files (numbered 1 to 4) and either A (meaning “immediate” endoscopic necrosectomy) or B (meaning “on-demand” endoscopic necrosectomy) is written in each file. For the first patient, the folder No. 1 and then the containing Word file No. 1 are opened to determine the patient’s group (A or B). For the 2nd to 4th patients, the Word files No. 2 to No. 4 from folder 1 are sequentially opened. For the 5th to 8th patients, the Word files No. 1 to No. 4 from folder 2 are sequentially opened; and this way, the random allocation process is continued for the next patients.

Blinding (investigator's opinion)
Single blinded

Blinding description
The physician who performs the interventions could not be blinded. The responsible physician for post-procedural care and the investigator who collects the data and evaluates the outcomes, however, would be blinded to the randomization assignment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Digestive Disease Research Institute (DDRI), Tehran University of Medical Scienc

Street address
Digestive Diseases Research Institute (DDRI), Shariati Hospital, North Kargar Street

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Postal code
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Approval date
2022-05-17, 1401/02/27

Ethics committee reference number
IR.TUMS.DDRI.REC.1401.008

Health conditions studied

1

Description of health condition studied
Acute pancreatitis; Infected walled off necrosis

ICD-10 code
K85.9

ICD-10 code description
Acute pancreatitis, unspecified

Primary outcomes

1

Description
Size of infected walled-off pancreatic necrosis

Timepoint

1 month and 3 months

Method of measurement

Abdominal computerized tomography (CT) scan

2

Description

Clinical symptoms and signs related to the infected walled off pancreatic necrosis

Timepoint

1 months and 3 months

Method of measurement

Patient interview

Secondary outcomes

1

Description

Complications after endoscopic necrosectomy

Timepoint

1 month and 3 months after stent placement

Method of measurement

Clinical evaluation and reviewing the patient's medical records

2

Description

Length-of-stay in hospital

Timepoint

1 month and 3 months after stent placement

Method of measurement

Reviewing the patient's medical records

3

Description

Number of necrosectomy sessions

Timepoint

1 month and 3 months after stent placement

Method of measurement

Reviewing the patient's medical records

4

Description

Mean time of necrosectomies

Timepoint

1 month and 3 months after stent placement

Method of measurement

Reviewing the patient's medical records

5

Description

Survival after 3 months

Timepoint

3 months after stent placement

Method of measurement

Interview with the patient or his/her relatives

6

Description

Rate of newly-diagnosed diabetes

Timepoint

1 month and 3 months after stent placement

Method of measurement

Laboratory evaluation (blood glucose)

Intervention groups

1

Description

Intervention group ("immediate" necrosectomy): Patients at this group will have endoscopic necrosectomy at the time of stent placement. The necrotic collection is identified with endoscopic ultrasonography (EUS); then transmural placement of cystogastrostomy stent under EUS guidance is performed. The type of stent, either "double pigtail plastic stent" or "lumen apposing metallic stent", is selected at the discretion of endoscopist. Immediately after stent placement, the track is dilated with a 15 mm through-the-scope (TTS) balloon; then, direct endoscopic necrosectomy is performed with CO2 insufflation for 45 to 90 minutes.

Category

Treatment - Other

2

Description

Control group ("immediate" necrosectomy): For patients in this group, endoscopic necrosectomy is not performed at the time of stent placement. Here again, the necrotic collection is identified with endoscopic ultrasonography (EUS); then transmural placement of cystogastrostomy stent under EUS guidance is performed. Again, the type of stent, either "double pigtail plastic stent" or "lumen apposing metallic stent", is selected at the discretion of endoscopist. Such patients may undergo endoscopic necrosectomy during follow up if clinically indicated (e.g. no improvement in inflammatory markers, persistant multi-organ failure, or recurrence of these indices after a primary improvement). The necrosectomy procedure, if any, is performed with CO2 insufflation for 45 to 90 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Morteza Hassanzadeh

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Digestive Disease Research Institute (DDRI), Shariati Hospital, Intersection of North Karegar street and

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tehran 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
Morteza Hassanzadeh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
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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
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 the individual patient data and codes used for study analysis would be shared online on request. All other data or documents of the study would also be released either as a published paper or its appendix, or as requested.
When the data will become available and for how long
Since 6 months after study results are published
To whom data/document is available
All who request
Under which criteria data/document could be used
Any kind of use of the study data will only be allowed with the permission of the corresponding author of the published paper from the study.
From where data/document is obtainable
Sending email to the corresponding author of the published paper from the study
What processes are involved for a request to access data/document
Sending an official email to the corresponding author and receiving his approval
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