Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the outcome of endoscopic retrograde cholangiopancreatography in pediatric patients with choledochal cysts

Protocol summary

Study aim
To compare the efficacy and safety of endoscopic retrograde cholangiopancreatography (ERCP) in the management of pediatric patients with choledochal cysts, in order to determine the role of ERCP as a potential alternative to surgery in selected cases

Design
Single-intervention, unblinded, randomized, phase 1 clinical trial on 45 patients

Settings and conduct
Surgical treatment of choledochal cyst using the less invasive endoscopic retrograde cholangiopancreatography method in the Pediatric Gastroenterology Endoscopy Department of Namazi Hospital after obtaining ethical approvals in children under 18 years of age.

Participants/Inclusion and exclusion criteria
This study will be conducted on pediatric patients (under 18 years of age) with choledochal cyst at Namazi Hospital in Shiraz. Inclusion criteria: Age 18 years or younger, primary treatment with endoscopic retrograde cholangiopancreatography ERCP, and availability of a complete medical record including images and follow-up information. Exclusion criteria: Incomplete medical records, presence of a severe concomitant disease (e.g., congenital heart disease) that affects treatment, and receiving both ERCP and surgery for the same disease episode (to avoid interference with the results).

Intervention groups
endoscopic retrograde cholangiopancreatography (ERCP) Group Type of intervention: Endoscopic procedure Brief description: Patients undergo diagnostic-therapeutic ERCP including sphincterotomy, stone extraction, stenting, and/or drainage of the choledochal cyst.

Main outcome variables
Complete resolution of clinical symptoms and no recurrence of symptoms during the follow-up period, without the need for additional intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260508069290N1**
Registration date: **2026-05-13, 1405/02/23**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-13, 1405/02/23**
Update count: **0**

Registration date
2026-05-13, 1405/02/23

Registrant information

Name
roghayeh soltani kalvanagh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 4344 5392

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r.mirsoltani@iran.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-10, 1405/02/20

Expected recruitment end date
2026-11-11, 1405/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the outcome of endoscopic retrograde cholangiopancreatography in pediatric patients with choledochal cysts

Public title
A review of surgical treatment of choledochal cysts in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with a confirmed diagnosis of choledochal cyst through clinical symptoms and imaging techniques such as Magnetic resonance cholangiopancreatography or ultrasound
Exclusion criteria:
Patients with incomplete medical records (lack of key operational or follow-up data)
Age
From **9 months** old to **18 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Karimkhan st. 36
City
Shiraz
Province
Fars
Postal code
7135744661
Approval date
2026-03-15, 1404/12/24
Ethics committee reference number
IR.SUMS.MED.REC.1405.007

Health conditions studied

1

Description of health condition studied
Choledochal Cysts
ICD-10 code
K80-K87
ICD-10 code description
Disorders of gallbladder, biliary tract and pancreas

Primary outcomes

1

Description
Relieving symptoms of choledochal cyst
Timepoint
Before the intervention to three months after the intervention
Method of measurement
Blood tests and clinical examinations

Secondary outcomes

1

Description
Decreased blood bilirubin
Timepoint
Before the intervention and up to three months after the intervention
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: In the endoscopy department of Namazi Hospital, the patient is placed under sedation or general anesthesia, the endoscope is inserted into the duodenum through the mouth. The papilla is removed and contrast is injected. If necessary, sphincterotomy, stone removal, stent placement, or cyst drainage are performed. The intervention usually takes 30 to 90 minutes
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital

Full name of responsible person
Dr Iraj Shahramian
Street address
Zand Street, Imam Hossein Square, Shiraz Medical School
City
Shiraz
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Postal code
7134845794
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+98 71 3233 5849
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irajshahramian@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Karim Khan Zand, next to the Red Crescent
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7134814336
Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
80
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
Shiraz University of Medical Sciences
Full name of responsible person
Roghayeh Soltani kalvanagh
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Some of the patients' endoscopic images may be published without the patient's identifying information
When the data will become available and for how long
Data access period begins after the publication of results for 12 months
To whom data/document is available
Researchers and interested parties are granted access to data with scientific justification
Under which criteria data/document could be used
If effective ideas are presented, it is not prohibited to conduct new analyses for research purposes
From where data/document is obtainable
Dr. Iraj Shahramian
What processes are involved for a request to access data/document
Submitting a proposal approved by the Ethics Committee of Shiraz University of Medical Sciences
Comments