

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Efficacy of Low Dose Hyoscine N-butyl Bromide Versus Usual Dose on Anti Motility Response and Cardiovascular Outcomes During Endoscopic Retrograde Cholangiopancreatography in patients with biliary tract disorder

Protocol summary

Study aim

Assessment the effect of low dose of hyoscine versus usual dose in anti motility response and cardiovascular outcomes during endoscopic retrograde cholangiopancreatography

Design

this is a randomized clinical trial with parallel group, double blinded study with sample size of 350 patients (175 patients for each group)

Settings and conduct

Yazd city, patient who come to state and private hospitals. Physician , personnel , and data collectors are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years, Underlying disease needs cholangiopancreatography, Existence of Duodenal peristaltism that Interference with canolation, Exclusion criteria: Previous cardiovascular problems (heart failure, myocardial infarction, second and third degree AV block), Acute pancreatitis and cholangitis before procedure, Severe hypotension (<100 mmhg), Pregnancy and breastfeeding, History of previous Allergy to Hyoscine,

Intervention groups

Group one receive 5mg (low dose) hyoscine N-butylbromide and group two (usual dose of hyoscine) receive 10 mg. The drug injects slowly intravenous and the spasmolytic effect of it is considered when the papilla is in enface view.

Main outcome variables

Assessment the minimum effective dose of hyoscine in anti motility and duration response , and cardiovascular outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180421039368N1**

Registration date: **2018-06-20, 1397/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-20, 1397/03/30**

Update count: **0**

Registration date

2018-06-20, 1397/03/30

Registrant information

Name

Hassan Salmanroghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

h.salmanroghani@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Efficacy of Low Dose Hyoscine N-butyl Bromide Versus Usual Dose on Anti Motility Response and Cardiovascular Outcomes During Endoscopic Retrograde Cholangiopancreatography in patients with billiary tract disorder
Public title	Effect of Hyoscine on Peristaltism and Cardiovascular Outcomes
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	age above 18 years Underlying disease needs cholangiopancreatography Existence of Duodenal peristaltism that Interference with canolation
Exclusion criteria:	Previous cardiovascular problems (heart failure, myocardial infarction, second and third degree AV block) Acute pancreatitis and cholangitis before procedure Severe hypotension (<100 mmhg) Pregnancy and breastfeeding History of previous Allergy to Hyoscine
Age	From 18 years old to 80 years old
Gender	Both
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator • Data analyser
Sample size	Target sample size: 350
Randomization (investigator's opinion)	Randomized
Randomization description	Eligible patients were randomized to two groups by Simple randomization method using computer-generated random numbers.
Blinding (investigator's opinion)	Double blinded
Blinding description	in our study, we inform the patients about the necessity of hyoscine injection. The patients and physician (performing the procedure) are both blinded to the injected drug dosage (low or usual). clinical care staff and analyzer are also blinded to the dosage of the drug.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics committee of yazd University of Medical Sciences
Street address	Ebn sina blvd, Shahid sadoughi hospital
City	Yazd
Province	Yazd
Postal code	8915814739
Approval date	2018-03-12, 1396/12/21
Ethics committee reference number	IR.SSU.MEDICINE.REC.1396.262
Health conditions studied	
1	
Description of health condition studied	Patients with underlying gallbladder and biliary tract disease
ICD-10 code	K80-K87
ICD-10 code description	Disorders of gallbladder, biliary tract and pancreas
Primary outcomes	
1	
Description	comparison of anti motility duodenal response
Timepoint	Before starting the procedure, five minutes after the injection of hyoscine, and at the end of procedure
Method of measurement	observing the duodenal motility (presence or absence of peristaltism) by physician during cholangiopancreatography (ERCP)
Secondary outcomes	
1	
Description	comparison of blood pressure changes, cardiac rate and rhythm and o2 satuartion changes
Timepoint	Before starting the procedure, five minutes after the injection of hyoscine, and at the end of procedure
Method of measurement	cardiac monitoring for blood pressure and heart rate and pulsoximetry for o2 saturation

Intervention groups

1

Description

Intervention group: patients who receive low dose of hyoscine N-butylbromide (5 mg) from Exir pharmaceutical company during cholangiopancreatography. The frequency of drug use depends on the duration of procedure and its interference with peristaltism.

Category

Treatment - Drugs

2

Description

Control group: patients who receive usual dose of hyoscin N-butylbromide (10mg) from Exir pharmaceutical company during cholangiopancreatography. The frequency of drug use depends on the duration of procedure and its interference with peristaltism.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid sadoughi hospital

Full name of responsible person

hassan salmanroghani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

dr massoud mirzaei

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dr_smm2020@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

hassan salmanroghani

Position

associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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 data can be share after blinding the patients

When the data will become available and for how long

after publishing the results of study will be available

To whom data/document is available

all of the researchers can access to study's data

Under which criteria data/document could be used

all the data will usable for analysis and comparison

From where data/document is obtainable

requisition must be send by an email to the corespondent author co respondent author : dr hassan salmanroghani
email: h.salmanroghani@ssu.ac.ir

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

after sending request email to corespondent author, data of study will send to applier

Comments