Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 billiary 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)

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+98 35 3822 4000

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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 commitee 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
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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
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

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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
requistion 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