Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of hyoscine and EMLA cream on Catheter related bladder discomfort (CRBD) in patients undergoing non-urologic surgery

Protocol summary

Study aim
Comparison of the effect of hyoscine and EMLA cream on Catheter related bladder discomfort in non-urological surgery

Design
Two arm parallel group randomized trial with blinded participants, outcome assessment and statistical analyst.

Settings and conduct
The study will assess the effectiveness of Hyoscine on CRBD compared to the EMLA group. The participants will assign equally to the groups. This study will carry out at Bohlool Hospital affiliated to Gonabad University of Medical Sciences. The participants, outcome assessment and statistical analyst will blind to the groups.

Participants/Inclusion and exclusion criteria
Having ASA class 1 or 2 , 18 to 60 years old, Elective surgery, general anesthesia and requires urinary catheterization, No history of bladder obstruction, overactive bladder, kidney and liver diseases, chronic pain, cerebrovascular disorders, cardiovascular diseases, psychosis, neurological bladder. Non-urological surgeries. No history of allergy to lidocaine or prilocaine and hyoscine, No cardiac dysrhythmia. No obvious cognitive impairment Do not take sedatives for a long time. No kidney or liver failure. No history of drug use. No untreated glaucoma, active bleeding, Paralytic ileus, chronic lung disease and secondary tachycardia due to heart failure. Medications used before and during anesthesia should be the same. Unwillingness to cooperate. Patients should also undergo urological surgery during the operation. Any effective intervention or medication in addition to medications used in the routine anesthesia process

Intervention groups
group 1: Hyoscine N-butyl bromide, at a dose of 20 mg intravenously within one minute before extubating. group 2, 5 g of EMLA cream and group 3 (control): 5 g of Lidocaine jell, both of these is made in Iran, applicating before placing a urinary catheter for a patient

Main outcome variables
Incidence of CRBD

General information

Reason for update
Adding control group to study, changing the measurement time and modifying randomization mode and sample size

Acronym
CRBD

IRCT registration information
IRCT registration number: **IRCT20210228050530N1**
Registration date: **2021-04-07, 1400/01/18**
Registration timing: **prospective**

Last update: **2021-06-03, 1400/03/13**
Update count: **1**

Registration date
2021-04-07, 1400/01/18

Registrant information

Name
Faezeh Khajeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5725 3729
Email address
fa.freedman1992@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-08-22, 1400/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of hyoscine and EMLA cream on Catheter related bladder discomfort (CRBD) in patients undergoing non-urologic surgery

Public title
The effect of hyoscine and EMLA cream on Catheter related bladder discomfort (CRBD)
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Having ASA class 1 or 2 according to the anesthesiologist record Age between 18 and 60 years Elective surgery with general anesthesia and requires urinary catheterization No history of bladder obstruction, overactive bladder, severe kidney and liver diseases, chronic pain, cerebrovascular disorders, cardiovascular diseases, psychosis, neurological bladder Non-urological surgeries. No history of allergy to lidocaine or prilocaine and hyoscine No cardiac dysrhythmia No obvious cognitive impairment Do not take sedatives for a long time No kidney or liver failure No history of drug use No untreated glaucoma, active bleeding, Paralytic ileus, chronic lung disease and secondary tachycardia due to heart failure Medications used before and during anesthesia should be the same
Exclusion criteria:
Unwillingness to cooperate Patients should also undergo urological surgery during the operation. Any effective intervention or medication in addition to medications used in the routine anesthesia process
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining written consent from the participants, the patients were selected through purposive sampling method and were randomly assigned to control and intervention groups based on the permutation blocks method. To do this, the letter C, B and A will be considered for the 2% lidocaine gel (control group), EMLA and Hyoscine + lidocaine groups, respectively. Possible modes in permutation blocks method are six modes include (BCA, ACB, ABC, BAC, CBA, and CAB). Each mode will be written on a card and the cards will be assigned the number one to six. Then 35 mode is selected by using a table of random numbers, 35 numbers between 1 and 6 will be selected. The resulting blocks will be listed in order. Then, based on the list, the selected patients are divided into three groups. In order to homogenize the gender, a separate list is prepared for each of those.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Prior to anesthesia and allocation to groups, for participants who meet the inclusion criteria will be described control and two intervention groups. The participants will be explained that they will allocate into two interventions or control groups. At the end of the study, they are informed about their group. The evaluator of primary (CRBD) and secondary outcomes (severity of CRBD) will be a person (Apart from the main researchers) who does not know the patient is in the intervention or control groups. One, two and three will assign to two interventions and control groups, respectively. Therefore, the statistical analyst will not aware of the study groups and only will know the groups as a code.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Gonabad University of Medical Sciences
Street address
No. 36, Alley 5, Resalat St
City
Gonabad
Province
Razavi Khorasan
Postal code
9691637744
Approval date
2021-02-27, 1399/12/09
Ethics committee reference number
IR.GMU.REC.1399.125

Health conditions studied

1

Description of health condition studied

Catheter related bladder discomfort

ICD-10 code

N32.8

ICD-10 code description

Other specified disorders of bladder

Primary outcomes

1

Description

Incidence of Catheter related bladder discomfort

Timepoint

In one, two, three and four hours after the end of anesthesia

Method of measurement

Checklist for the incidence of Catheter related bladder discomfort

Secondary outcomes

1

Description

Severity of CRBD

Timepoint

In one, two, three and four hours after the end of anesthesia.

Method of measurement

Checklist of severity of CRBD of Catheter related bladder discomfort

Intervention groups

1

Description

Intervention group 1: Hyoscine N-butyl bromide made in Iran, Elixir Company, at a dose of 20 mg intravenously within one minute before extubating of a patient under non-urological surgery.

Category

Prevention

2

Description

Intervention group 2: 5 g of EMLA cream made in Iran, Iran Daroo Company before placing a urinary catheter for a patient undergoing non-urological surgery

Category

Prevention

3

Description

Control group: 5 g lidocaine jell made in Iran, Iran Daroo Company before placing a urinary catheter for a patient undergoing non-urological surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohlool Hospital

Full name of responsible person

Saeed Mehrabi

Street address

No. 36, Alley 5, Resalat St

City

Gonabad

Province

Razavi Khorasan

Postal code

9691637744

Phone

+98 51 5725 3729

Email

fa.freedman1992@gmail.com

Web page address

http://bohlool.gmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Shahla Khosravan

Street address

No. 36, Alley 5, Resalat St.

City

Gonabad

Province

Razavi Khorasan

Postal code

9691637744

Phone

+98 51 5725 3729

Email

fa.freedman1992@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Faezeh Khajeh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 36, Alley 5, Resalat St.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691637744
Phone
+98 51 5725 3729
Email
fa.freedman1992@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Faezeh Khajeh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 36, Alley 5, Resalat St.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691637744
Phone
+98 51 5725 3729
Email
fa.freedman1992@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Faezeh Khajeh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 36, Alley 5, Resalat St.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691637744
Phone
+98 51 5725 3729
Email
fa.freedman1992@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Thesis report All research information will be published after being unidentified.
When the data will become available and for how long
Since 1401
To whom data/document is available
Everyone can request research results.
Under which criteria data/document could be used
Upon formal request through other members of the research team
From where data/document is obtainable
Library of Gonabad University of Medical Sciences
What processes are involved for a request to access data/document
An official request to Gonabad University of Medical Sciences
Comments