Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2018

Bupivacaine and hydrocortisone effect on post operative pain after laparoscopic cholecystectomy

Protocol summary

Summary
The aim of this study was to determine the effect of topical bupivacaine and hydrocortisone use effect in gallbladder bed for preventing post operative pain after laparoscopic cholecystectomy in patient with choronic cholecysititise. This clinical study is a single blind, placebo-controlled, single center. 90 patient candidate laparoscopic cholecystectomy due to Inclusion criteria: Laparoscopic cholecystectomy due to symptomatic patients who were carrying Lithiasis Exclusion criteria: allergy to local anesthetics and drugs; morbid obesity; advanced respiratory diseases; Kidney disease; blood diseases; Liver disease; Cardiovascular disease; Chronic use of drugs, beta-adrenergic receptor antagonists; pregnant women; The mentally retarded cases selected randomly divide into three groups of 30 people. first group receive 100 mg hydrocortisone, second group 10 mL of bupivacaine solution%.5 and the third 10 cc of normal saline topically . VAS questionnaires are checked at six and twelve hours after surgery, Reduce pain, is responding to treatment.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2017012110222N7**
Registration date: **2017-02-06, 1395/11/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2017-02-06, 1395/11/18

Registrant information

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Recruitment status
Recruitment complete

Funding source
Shahrekord University of Medical Sciences

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Bupivacaine and hydrocortisone effect on post operative pain after laparoscopic cholecystectomy

Public title
Comparing the topical effect of bupivacaine and hydrocortisone in gallbladder bed on post operative pain following laparoscopic cholecystectomy among chronic cholecystitis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclution criteria: Laparoscopic cholecystectomy due to symptomatic patients who were carrying Lithiasis Exclusion criteria: allergy to local anesthetics and drugs; morbid obesity; advanced respiratory diseases; Kidney disease; blood diseases; Liver disease; Cardiovascular disease; Chronic use of drugs, beta-adrenergic receptor antagonists; pregnant women; The mentally retarded

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
None

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
Shahrekord, Shahrekord University of Medical Sciences
City
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Country
Iran (Islamic Republic of)
Postal code
Approval date
2016-11-27, 1395/09/07
Ethics committee reference number
IR.SKUMS.REC.1395. 209

Health conditions studied

1

Description of health condition studied
cholelithiasis
ICD-10 code
k80.1
ICD-10 code description
Calculus of gallbladder with other cholecystitis

Primary outcomes

1

Description
pain relief
Timepoint
6 and 12 hours after surgery
Method of measurement
questionaire

Secondary outcomes

empty

Intervention groups

1

Description
The first group receive 100 mg hydrocortisone topically during surgery .
Category
Treatment - Drugs

2

Description
The second group receive 10 mL of bupivacaine solution%.5 topically during surgery .
Category
Treatment - Drugs

3

Description
The Third group receive 10 cc of normal saline topically during surgery .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital in Shahrekord
Full name of responsible person
Babak Alavi Farzaneh
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Shahrekord, Shahrekord University Of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahrekord University of Medical Science
Full name of responsible person
Dr. Kamal Solati
Street address
Shahrekord, Shahrekord University of Medical Sciences
City
Shahrekord

Country
Iran (Islamic Republic of)
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shahrekord University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty