Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparative effect of paracetamol vs music playing on pain in extra corporeal shock wave lithothrepsy

Protocol summary

Summary

Extracorporeal shock wave lithotripsy is a non invasive procedure allows urinary stones to be broken.The shock wave because pain and discomfort in entry site and deep viscera. A cooperative patient is essential in maintaining stone targeting for optimal fragmentation during extra corporeal shock wave lithotripsy (ESWL). Therefore, it is important to choose an appropriate analgesic, sedation with minimal adverse effects intravenous acetaminophen is a non opioid analgesic and primary act on central nervous system by way of cyclooxygenase inhibition. All the healthy patient who candidate only for ESWL can come to study. The exclusion criteria are contraindication to use opioids; severe chronic respiratory disease and severe obesity.There are no need to use placebo because study is not blind. In this study patients are divided in three groups. Group A receive only sufentanyl and propofol. Group B receive sufentanyl and propofol plus paraacetamol. Group C receive sufentany and propofol plus music playing. Pain evaluation is by numerical pain scale every five minute during ESWL. The primary end point of this study is to compare effect of intravenous acetaminophen with music playing on pain perception in ESWL. The secondary end point is s occurrence of respiratory depression in PACU

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301151936N10**
Registration date: **2013-01-27, 1391/11/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-01-27, 1391/11/08

Registrant information

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2013-01-29, 1391/11/10

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative effect of paracetamol vs music playing on pain in extra corporeal shock wave lithothrepsy

Public title

The comparative effect of paracetamol vs music playing on pain in extra corporeal shock wave lithothrepsy

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria are: the patients who candidate only for ESWL and American Society of Anesthesiologist(ASA)score I or II. The exclusion criteria are contraindication to use opioids; severe chronic

respiratory disease and severe obesity.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bushehr University of Medical Sciences Ethics Committee

Street address
Bushehr -Bushehr University of Medical Sciences

City
Bushehr

Postal code

Approval date
2012-11-21, 1391/09/01

Ethics committee reference number
B-91-14-3

Health conditions studied

1

Description of health condition studied
Pain durinng ESWL

ICD-10 code
N99.9

ICD-10 code description
Postprocedural disorder of genitourinary system, unspecified

Primary outcomes

1

Description
Pain during ESWL

Timepoint
45 minutes

Method of measurement
Numerical analogous pain scale

Secondary outcomes

1

Description
Occurence of respiratory depression

Timepoint
60 minutes

Method of measurement
Pulse oximetry

Intervention groups

1

Description
Patient divided to 3 equals groups. Group A(n=45) (control group) receive 30 micrograms per kilogeram per minute propofol plus10 sufentanli. Pain assessed every 5 minute by numerical pain score(0= no pain,10=severe pain) and in situation that it will be over 3 a rescue doses of sufentanil(2.5 micrograms) will be injected.

Category
Prevention

2

Description
Patient divided to 3 equals groups. Group B(n=45) (intervention group) receive 30 micrograms per kilogeram per minute propofol plus 10 micrograms sufentanil and 15 micrograms of paraacetamol per minute. Pain assessed every 5 minute by numerical pain score(0= no pain,10=severe pain) and in situation that it will be over 3 a rescue doses of sufentanil(2.5 micrograms) will be injected

Category
Prevention

3

Description
Patient divided to 3 equals groups. Group C(n=45) intervention group)receive 30 micrograms per kilogram per minute propofol plus 10 micrograms of sufentanil and music playing during ESWL. Pain assessed every 5 minute by numerical pain score(0= no pain,10=severe pain) and in situation that it will be over 3 a rescue doses of sufentanil(2.5 micrograms) will be injected

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
BENTOLHODA HOSPITAL
Full name of responsible person
Dr.najafianaraki
Street address
bushehr-fatemezahra hospital
City
bushehr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Dr majid asadi
Street address
Bushehr university of medical science
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bushehr University of Medical Sciences
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

Contact
Name of organization / entity
Bushehr University of Medical Sciences
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Fax
Email
Web page address

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