Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison effect of intravenous Acetaminophen and Fentanyl as a premedicant for intra-operative and post-operative pain reduction in Trans Urethral Lithotripsy surgery.

Protocol summary

Summary

Study is done as clinical trial on 80 patients with age of minimum 18 years, in ASA class of I and II, and candidate for Trans Urethral Lithotripsy (TUL) as elective and under general anesthesia at the Velayat hospital of Qazvin from June 2017 to Feb 2018. Patients in parallel design are divided randomly (colorful cards) in two groups (A, F). 15 min before entering to operation room, A group receives 15 mg/kg intervenes Astaminiphon diluted to volume of 100 ml with Normal saline, and F group infusions 100 ml Normal saline as placebo. All patients will be placed under standard monitoring including NIBP, ECG, Puls oximetry and Oxygen saturation. Then patients receive 0.02 mg/kg Midazolam as premedication. Before Anesthesia induction, F group receives 1.5 mg/Kg intervenes Fentanyl, and A group receives 2 ml Normal saline. Patients are pre oxygenated for 3 min. For the Anesthesia induction, 2 mg/kg intervenes Propofol is prescribed. Patients are ventilated with mask and following anesthesia is done with infusion 100 micro gr/Kg Propofol and N2O- O2 gases with proportional 50-50. After conscious and also 5, 15 and 30 minutes after interring to the recovery, pain severity is evaluated via Visual Analog Scale (VAS). After interring to ward, pain severity is followed up to 24 hours after surgery, and 25 mg inter muscle Petedine is injected per 8 hours if needed (VAS˃3).50-50. After conscious and also 5, 15 and 30 minutes after interring to the recovery, pain severity is evaluated via Visual Analog Scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120331215N1**
Registration date: **2017-07-26, 1396/05/04**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-07-26, 1396/05/04

Registrant information

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Fatemeh Hosseini Fard
Name of organization / entity
Qazvin University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effect of intravenous Acetaminophen and Fentanyl as a premedicant for intra-operative and post-operative pain reduction in Trans Urethral Lithotripsy surgery.

Public title
Comparison effect of Acetaminophen and Fentanyl on the pain reduction during and after Trans Urethral Lithotripsy surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age of 18 years and more; patients in class of I and II based on ASA; patients at risk for surgery. Exclusion criteria: History of liver disease; History of allergic reactions or intolerance to the studied drugs; Narcotic addiction; ASA class of III and more; History of narcotic taking before surgery; keratinin more than 1.5 mg/dl; Insulin-dependent diabetes; History of taking antidepressants or anticonvulsants; History of Gastroesophageal reflux and Hernia Hyatal; Body Mass Index≥35; Pregnancy; Alzheimer's disease or mental retardation.
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committe of Qazvin University of Medicine Sciences
Street address
Bahonar Blvd., Qazvin
City
Qazvin
Postal code
Approval date
2016-07-13, 1395/04/23
Ethics committee reference number
IR.QUMS.REC.1395.93

Health conditions studied

1

Description of health condition studied
Trans Urethral Lithotripsy
ICD-10 code
N20.1
ICD-10 code description
Ureteric stone

Primary outcomes

1

Description
Pain severity
Timepoint
Intra-operative and post-operative in recovery and 24 hours postoperative in surgery ward
Method of measurement
intra-operative with controlling blood pressure change and hurt rate more than 20% baseline and visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receiving 15 mg/kg intervenes Acetaminophen diluted with Normal saline to volume of 100 ml before surgery. Receiving 1.5 micro gr/ kg intervenes Fentanyl intra-operation.
Category
Treatment - Drugs

2

Description
Control group: Receiving 100 ml Normal saline before surgery. Receiving 2 ml Normal saline intra-operation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Dr. Fatemeh Hosseini Fard
Street address
Velayat Hospital, 22 Bahman Blvd., Qazvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of Reseach, Qazvin University of Medical Sciences
Full name of responsible person
Dr. Amir Peymani
Street address
Bahonar Blvd., Qazvin
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Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of Reseach, Qazvin 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
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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