

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of post-operative infusion of ultra-low dose of naloxone on post hystrectomy morphine consumption, side effects and pain intensity

Protocol summary

Summary

In this prospective, randomized, double-blind study, we evaluated the effect of an ultra-low dose of naloxone infusion on the amount of postoperative morphine consumption and the reduction of opioid induced side effects post- operative nausea and vomiting(PONV) and pruritus. Ninety patients scheduled for total abdominal hysterectomy and classified as American Society of Anesthesiologists physical status 1 or 2 were enrolled in the study. They were randomized to either saline (control, n=45) or naloxone 0.2µg.kg-1.h-1(n=45) for 24 hours. Standardized general anesthetics were administered in both groups. In the Recovery room, patients received morphine by patient-controlled analgesia. Ultra- low dose naloxone was infused intravenously at 0.2µg.kg-1.h-1 for 24 hours, in the intervention group and saline in control group. Morphine use, numeric rating score (NRS) for pain intensity, nausea, vomiting, pruritus, and requests for antiemetic were recorded at baseline , 30min and every 4 hour up to 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012025175N4**

Registration date: **2011-02-10, 1389/11/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-02-10, 1389/11/21

Registrant information

Name

Ali Movafegh

Name of organization / entity

Dr. Shariati Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2373

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movafegh@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2010-12-02, 1389/09/11

Expected recruitment end date

2011-06-06, 1390/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of post-operative infusion of ultra-low dose of naloxone on post hystrectomy morphine consumption, side effects and pain intensity

Public title

Effects of Naloxane on Pain Control in Post operative Management of Hysterectomy Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1-ASA physical status I and II scheduled for total abdominal hysterectomy with standadized general aneshtesia/ 2-Age between 35-65 years old
Exclusion criteria : 1-Hepatic or Renal failure, Heart diseases, 2- history of drug allergy, substance abuse (including opioids and benzodiazepines) , 3-morbid

obesity, 4-history of postoperative nausea and vomiting(PONV),history of motion sickness 5- smokers

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics Committee, Faculty of Medicine

Street address

Faculty of Medicine, Tehran University of Medical Sciences and Health Care

City

Tehran

Postal code

Approval date

2010-12-03, 1389/09/12

Ethics committee reference number

374/1892

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.0

ICD-10 code description

acute pain

Primary outcomes

1

Description

Morphine Consumption

Timepoint

0 ,30 min,1hr, 2hr, 4hr, 8hr, 16hr, 20hr, 24hr after surgery

Method of measurement

Opioid registration by milligrams

2

Description

Pain Intensity

Timepoint

0 ,30 min,1hr, 2hr, 4hr, 8hr, 16hr, 20hr, 24hr after surgery

Method of measurement

NRS(Numeric Rating Score)

Secondary outcomes

1

Description

duration of operation

Timepoint

during the operation

Method of measurement

operating chart

2

Description

Intraoperative Fluid received

Timepoint

during the operation

Method of measurement

Crystalloid Fluid registration chart

3

Description

Pruritus

Timepoint

0 ,30 min,1hr, 2hr, 4hr, 8hr, 16hr, 20hr, 24hr after surgery

Method of measurement

Numeric Rating score (NRS)

4

Description

Post operative Nausea and Vomiting

Timepoint

0 ,30 min,1hr, 2hr, 4hr, 8hr, 16hr, 20hr, 24hr after surgery

Method of measurement

NRS (Numeric Rating score)

Intervention groups

1

Description

Intervention: (Naloxone Group n=45) Before surgery, patients in group N received a loading dose of Naloxone (1mg. kg-1) then In the recovery room, patients were attached to a patient controlled analgesia (PCA) device. The PCA device was programmed to achieve patient's comfort by delivery on demand. The device contained 30 mg Morphine in 30 ml saline 9% (1mg/ml). After a loading dose of intravenous Morphine 40µg/kg ,a bolus dose of 1mg Morphine was administered with lockout interval of 8 min with no preset of maximum dose.

Category

Treatment - Drugs

2

Description

Control group (n=45): Before the surgery, patients in this group received Saline, in 2 mL then in the recovery room, patients were attached to a patient controlled analgesia (PCA) device. The PCA device was programmed to achieve patient's comfort by delivery on demand. The device contained 30 mg Morphine in 30 ml saline 9% (1mg/ml). After a loading dose of intravenous Morphine 40µg/kg, a bolus dose of 1mg Morphine was administered with lockout interval of 8 min with no preset of maximum dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Ali Shariati Hospital

Full name of responsible person

Dr.Ali Movafegh

Street address

Shariati Hosp, North Karegar Ave,

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Shahin Akhoundzade

Street address

Tehran University of Medical Sciences, Vice Chancellor

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences and Health Services

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

Department of Anesthesiology, Tehran University of medical sciences

Full name of responsible person

Dr Ali Movafegh

Position

Associate Prof.

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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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