

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparative study of the analgesic effect of Morphine patient control analgesia pumps and Fentanyl Trans-dermal patches in acute post operative pain management in addicted patients

Protocol summary

Summary

With the aim of comparison of the analgesic effect of Morphine pumps and Fentanyl patches in acute post operative pain control, we will enroll 300 patients (150 addict patient and 150 non addict patient), aged between 15 to 60 years old which have been undergone orthopedic surgeries in Shahid Kamyab accident hospital in 2013 to 2014 in this study. After filling the inclusion criteria such as age, head trauma or unconsciousness, they are fully informed and sign the ethical committee forms. Based on the type of surgery (major, minor and moderate), patients will be randomly divided into two groups, for post operation pain control: in group A, patients will receive IV- Morphine PCA pump. Each pump is filled by 20 mg Morphine diluted in 100 cc normal saline and is set in 1mg/h infusion rate. One bolus dose could be added by the patient if he/she felt undesirable pain. In group B Fentanyl transdermal patches with total dose of 25 µg are used. Regarding the delay action of the patches, they are attached upon the patients arm 18 h before the operation. Duration and type of drug addiction history by a trained research nurse was not involved in the treatment process will be recorded. The severity of the pain will be registered according to Visual Analogue Scale in specially designed forms by pain-trained nurses in two steps, first after the surgery and before the beginning of analgesic effect; no other analgesic drug will be used at this time. So 24 h after the surgery pain will be assessed again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404297829N5**

Registration date: **2016-11-27, 1395/09/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-27, 1395/09/07

Registrant information

Name

Hami Ashraf

Name of organization / entity

Mashhad University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Orthopedic Research Center and Vice chancellor for research Mashhad University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2015-04-08, 1394/01/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the analgesic effect of Morphine patient control analgesia pumps and Fentanyl Trans-dermal patches in acute post operative pain management in addicted patients

Public title

Comparison of two analgesic methods in control of Post-operative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with post operative pain; aged from 15 to 60 years; cooperative psychologically.

Exclusion criteria: patients who need another analgesic method; head trauma or unconsciousness; any medical contraindication; aged beneath 15 or above 60 year

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Blinding: due to the intervention of the study, blinding for patients is impossible. The nurse who is responsible for the pain interview and patient information and also the statistician responsible for analyzing the data were blinded to the intervention. Randomization: using a random number table, patients were randomly allocated into two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Central building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah St., Mashhad

City

Mashhad

Postal code

Approval date

2016-09-24, 1395/07/03

Ethics committee reference number

IR.MUMS.REC.1390.803

Health conditions studied

1

Description of health condition studied

Acute post operation pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

patients' pain

Timepoint

30 minutes after the surgery and then 24 hours later

Method of measurement

0 to 10 visual analogue scale

2

Description

patients' satisfaction

Timepoint

24 hours after the surgery

Method of measurement

0 to 100 designed scale

3

Description

Addiction

Timepoint

The first day of admission

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups

1

Description

Morphine pump group: 100cc pumps will be filled with 20mg morphine Diluted in 100cc normal saline. It will be set on 1mg/h infusion rate. One bolus dose could be added by the patients if he/she needs more analgesia. It was made by AutoFuser Disposable Pain Pump Product, Ace Medical Co, Gyeonggi-Do, Korea.

Category

Treatment - Drugs

2

Description

Fentanyl patch group: Fentanyl patches with total dose

of 25mg will be attached upon the patients' arm 18h before the surgery due to 18h delayed action of them. It was made by Fentanyl ITS; lonsys TM, Janssen Pharmaceutica NV, Beerse, Belgium.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Shahid Kamyab Hospital

Full name of responsible person

Ali Birjandinejad

Street address

Orthopedic Research Center, Shahid Kamyab Hospital, Nakhrisi crossroad, Fadaeyan Eslam St, Mashhad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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 Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Hami Ashraf

Position

Medical doctor

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Associated professor

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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