

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparative study of the analgesic effect of Morphine Patient control analgesia pumps and Trans-dermal Fentanyl patches in Acute Post Operative Pain management in patients referred to Mashhad Shahid Kamyab trauma center

Protocol summary

2012-08-17, 1391/05/27

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 200 patients, aged between 15 to 60 years old which have been undergone orthopedic surgeries in Shahid Kamyab accident hospital in this study. After filling the inclusion criteria, they are fully informed and sign the ethical committee forms. 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. 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: **IRCT201111147829N2**

Registration date: **2012-08-17, 1391/05/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Hami Ashraf

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1842 4685

Email address

ashrafh821@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Mashhad University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-08-03, 1391/05/13

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 Trans-dermal Fentanyl patches in Acute Post Operative Pain management in patients referred to Mashhad Shahid Kamyab trauma center

Public title

Morphine pump versus trans-Dermal Fentanyl patch In Post surgery Pain control

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 **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

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

Vice chancellor for research Mashhad University of Medical Sciences

Street address

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

City

Mashhad

Postal code

Approval date

2012-03-03, 1390/12/13

Ethics committee reference number

900355

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

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

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.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Shahid-Kamyab accident hospital

Full name of responsible person

Ali Birjandinejad

Street address

Orthopedic and trauma research center, Shahyd Kamyab hospital, Nakhrisi crossroad, Mashhad

City
Mashhad

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

Street address

Vice chancellor of research, central building of Mashhad university of medical sciences (Ghoreishi) - Daneshgah Str - Mashhad

City

mashhad

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

Other areas of specialty/work

Street address

No 6, Building 121, Mirdaman Str, Kuhsangi Ave, Mashhad

City

mashhad

Postal code

Phone

+98 51 1842 4685

Fax

Email

ashrafh821@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Orthopedic and trauma research center-- Mashhad University of Medical Sciences

Full name of responsible person

Ali Birjandinejad

Position

associated professor

Other areas of specialty/work

Street address

Shahyd Kamyab hospital, Nakhrisi crossroad

City

Mashhad

Postal code

Phone

+98 51 1802 6122

Fax

Email

birjandinejada@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hami Ashraf

Position

medical doctor

Other areas of specialty/work

Street address

No 6, Building 121, Mirdamad Str, Kuhsangi Ave, Mashhad

City

Mashhad

Postal code

Phone

+98 51 1842 4685

Fax

Email

mrhami_ashraf@yahoo.com

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