

# 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**

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## Person responsible for scientific inquiries

### Contact

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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**

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## Person responsible for updating data

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**Position**

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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*