

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1842 4685

###### Email address

ashrafh821@mums.ac.ir

##### 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

**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 St. - 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

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Orthopedic Research Center- Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Associated professor

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**Position**

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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*