

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of analgesic effects of nebulized morphine with fentanyl transdermal patch and oral methadone for cancer patients in terminal stages

Protocol summary

Study aim

Comparison of analgesic effect of nebulized Morphine, Fentanyl transdermal patch and oral Methadone in end stage cancer patients.

Design

In this study 90 eligible cancer patients who referred to Sayed al-shohada hospital (A teaching hospital of the Isfahan University of Medical Sciences) were selected according to study criteria and then divided in 3 groups (each group 30 patients) in random order.

Settings and conduct

The patients were followed up for three days. Severity of pain was measured in the beginning of the first day before administering the first dose and again evaluated at the end of the day. This procedure repeated for two more days at the beginning and end of each days. For each patient a code was allocated. Analyzer and assessor were unaware about classifications of codes.

Participants/Inclusion and exclusion criteria

Criteria for entering the study including being older than 18, awareness of patient about his situation, kind of the cancer, having no allergy to Opioids, not having hypotension (systolic blood pressure lower than 110mmHg), no hypoxemia (Oxygen saturation lower than 90 percent in room temperature), no Rhinitis, no liver and kidney disorders, no Hypothyroidism or Addison's disease and no Prostatic hypertrophy.

Intervention groups

End stage cancer patients who suffering from moderate or severe pain divided in 3 groups: for group 1 nebulized Morphine was prescribed for analgesia. for group 2 oral Methadone was prescribed for analgesia. For group 4 Fentanyl trans-dermal patch was prescribed for analgesia.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171211037834N1**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **retrospective**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Mahdi ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3771 8986

Email address

m.ebrahimi@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2017-09-22, 1396/06/31

Trial completion date

empty

Scientific title

The comparison of analgesic effects of nebulized morphine with fentanyl transdermal patch and oral methadone for cancer patients in terminal stages

Public title

The analgesic effect of Nebulized Morphine, Fentanyl Transdermal Patch and Oral Methadone

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from moderate or severe pain Patient awareness about his/her situation and illness Suitable Glasgow Coma Scale (GCS) for patient cooperation

Exclusion criteria:

Allergy to Opioids Hypotension(Systolic Blood pressure lower than 110 mmHg) Bradypnea (respiration rate less than 12 times per minutes) Hypoxemia (Oxygen saturation lower than 90 percent in room temperature) Rhinitis Liver and kidney disorders Hypothyroidism Prostate hypertrophy Addison's disease

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple personal randomization by random allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

First of all for each patient a code was allocated. Codes allocations explain as follow: 101 to 130: allocated to Morphine nebulized (group 1) 201 to 230: allocated to Fentanyl trans-dermal patch (group 2) 301 to 330: allocated to oral Methadone (group 3) A person as assessor was going to patient's bedside and asked about his/her pain severity (with Visual Analog Scale). The questioner kept unaware about the kind of medicines and the group of each patients (nebulized Morphine, Fentanyl trans-dermal patch, oral Methadone) and also about the codes classification. He was just adding the codes in the form. Analyzer also did not know about classifications of codes and just was dividing the patient in groups according codes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, P.O. Box 319, Hezar-Jerib Ave., Isfahan, IR Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-05-03, 1396/02/13

Ethics committee reference number

ir.mui.rec.1396.3.129

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

2

Description of health condition studied

Lung cancer

ICD-10 code

C34

ICD-10 code description

Malignant neoplasm of bronchus and lung

3

Description of health condition studied

Prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

4

Description of health condition studied

Liver cancer

ICD-10 code

C22.0

ICD-10 code description

Liver cell carcinoma

5

Description of health condition studied

Colon cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

6

Description of health condition studied

Stomach cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

7

Description of health condition studied

Uterus cancer

ICD-10 code

C55

ICD-10 code description

Malignant neoplasm of uterus, part unspecified

8

Description of health condition studied

Bladder cancer

ICD-10 code

C67

ICD-10 code description

Malignant neoplasm of bladder

Primary outcomes

1

Description

Pain

Timepoint

At the beginning of the study (before the intervention) and at the beginning and end of each day for 3 days.

Method of measurement

Visual Analog Score that is numbered from 0 to 10.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: nebulized group, received nebulization of 20-mg Morphine, repeated every 10minutes with a maximum of 3 nebulizations.

Category

Treatment - Drugs

2

Description

Intervention group: Fentanyl group, received 0.6 mg of transdermal Fentanyl. The transdermal patch was changed every 72 hr.

Category

Treatment - Drugs

3

Description

Control group: oral Methadone group, were treated with oral Methadone (maximum dose of 45 mg/day) divided in three doses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayed-Al-Shohada hospital

Full name of responsible person

Mahdi Ebrahimi

Street address

Farshadi Alley, Khayam St

City

Isfahan

Province

Isfahan

Postal code

0000000000

Phone

+98 31 3235 0214

Email

m.ebrahimi@resident.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Attar

Street address

No4 building, Esfahan University of Medical Sciences, Hezar Jirib Ave

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address
http://research.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mahdi Ebrahimi

Position
Emergency medicine Resident

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address
No. 41, Ashrafi Isfahan Blvd.

City
Isfahan

Province
Isfahan

Postal code
0000000000

Phone
+98 31 3771 8986

Email
m.ebrahimi@resident.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mahdi Ebrahimi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address

Alzahra hodpital, Shohadaye sofe ave

City
Isfahan

Province
Isfahan

Postal code
8174675731

Phone
+98 31 3771 8986

Fax

Email
m.ebrahimi@resident.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mahdi Ebrahimi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Emergency Medicine

Street address
Alzahra hodpital, Shohadaye sofe ave

City
Esfahan

Province
Isfahan

Postal code
8174675731

Phone
+98 31 3771 8986

Fax

Email
m.ebrahimi@resident.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All of data, after unrecognizable process are accessible.

When the data will become available and for how long

access is possible 1 year after publish.

To whom data/document is available

Access is possible just for academic research centers.

Under which criteria data/document could be used

Data Analysis is allowed and there is not any specific limitation.

From where data/document is obtainable

Requests should be send to electronic mail and attach

documented mail from associated research center

What processes are involved for a request to access data/document

After request receiving, inquiry mail will be send for associated research center. After confirmation, data will be send for applicant

Comments