Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 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 trams-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
Isfehan

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
Isfehan
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
Isfehan
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 Ebrahini
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
Isfehan
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
Isfehan
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
Isfehan
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