Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparing the analgesic response of intravenous Morphine versus Fentanyl for adult traumatic patients in emergency department

Protocol summary

Study aim

1- To compare the pain reduction between the patients received morphine vs. fentanyl 2- To compare time to lowest pain score between the patients received morphine vs. fentanyl 3- To compare changes in vital sign between the patients received morphine vs. fentanyl 4- To compare the incidence of adverse events between the patients received morphine vs. fentanyl

Design

Parallel group, single blind, randomised controlled trial

Settings and conduct

The study will be performed on 180 consecutive adult trauma patients with acute pain who were brought to the ED of Nemazee hospital. The sample size will be chosen on the basis of a previous randomized controlled study that compared pain response between opioids. The patients will be selected to use of intravenous opioids according to the judgment of the ED attending physician. Then, they will be randomly allocated to receive a single dose of intravenous morphine (0.1 mg/kg) or fentanyl (5 µg/kg) administered in a single-blind fashion. The patients will not be aware about type of opioids.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have an initial pain score of 4 or more (0 = no pain and 10 = worst possible pain) on the Numerical Rating Scale (NRS) upon presentation; Age more than 18 years; Initial oxygen saturation greater than 95%; Patients with a GCS score of 15. Exclusion Criteria: Systolic blood pressure less than 90 mmHg; Known pregnancy; Patients with chronic pain syndromes (such as sickle cell disease or fibromyalgia); Cognitive impairment; Known allergy to either fentanyl or morphine.

Intervention groups

Adult trauma patients in the emergency department

Main outcome variables

The primary outcome measure will be pain reduction on the NRS after administration of morphine or fentanyl; Time to lowest pain score will be also considered as secondary outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180608040013N1**
Registration date: **2019-07-17, 1398/04/26**
Registration timing: **retrospective**

Last update: **2019-07-17, 1398/04/26**
Update count: **0**

Registration date

2019-07-17, 1398/04/26

Registrant information

Name
Najmeh Zarei jelyani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2018-12-22, 1397/10/01

Trial completion date

2018-12-22, 1397/10/01

Scientific title
Comparing the analgesic response of intravenous Morphine versus Fentanyl for adult traumatic patients in emergency department

Public title
Pain control with intravenous Morphine versus Fentanyl in adult traumatic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have an initial pain score of 4 or more (0 = no pain and 10 = worst possible pain) according to the Numerical Rating Scale (NRS) upon presentation. Age more than 18 years Initial oxygen saturation greater than 95% Patients with a GCS score of 15

Exclusion criteria:
Systolic blood pressure less than 90 mmHg Known pregnancy Patients with chronic pain syndromes (such as sickle cell disease or fibromyalgia) Cognitive impairment Known allergy to either fentanyl or morphine

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **180**
Actual sample size reached: **167**

Randomization (investigator's opinion)
Randomized

Randomization description
We used block randomization in the current study. Each block size was 2 by 2, and totally 45 blocks were considered. The acceptable sequences for packages within each block were: 1) AABB, 2) ABAB, 3) BBAA, 4) BABA, 5) ABBA, and 6) BAAB. Then each of them had been marked from 1 to 6 as above. After that, the packages within blocks were sequentially numbered from 1 to 180. Participant were consecutively numbered from 1 to 180, based on the time of admission and hospital registration code. Allocation was performed by blindly matching the patients' number and package. Randomization sequence and concealment were performed by emergency medicine attending. Allocation and matching of the participants' number to the package number in order to receive the intervention was performed by emergency medicine resident.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Two set of 90 sterile, colorless and ready to inject 10cm3 syringes were prepared and name syringe A (morphine) and syringe B (fentanyl) before concealment. According to block randomization, each patients were received syringe A or B. So, the patients, physicians, nurses, as well as data analyzer were blinded to kind of analgesics were used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Karim khan zand Ave, Shiraz University of Medical Sciences

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Shiraz

Province
Fars

Postal code
7186836388

Approval date
2018-06-18, 1397/03/28

Ethics committee reference number
IR.SUMS.MED.REC.1397.133

Health conditions studied

1

Description of health condition studied
Adult traumatic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain reduction based on the Numerical Rating Scale (NRS)

Timepoint
At baseline, 5, 10, 30, 120 minutes post baseline

Method of measurement
Numerical Rating Scale (NRS)

Secondary outcomes

1

Description
Time to lowest pain score
Timepoint
From baseline to 2 hours post baseline
Method of measurement
Stopwatch

Intervention groups

1

Description
Intervention group: A single dose of intravenous morphine (0.1 mg/kg)
Category
Treatment - Drugs

2

Description
Control group: A single dose of intravenous fentanyl (5 µg/kg)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Najmeh Zarei Jelyani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
96.01.01.14253
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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Full name of responsible person
Najmeh Zarei Jelyani
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Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available