Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of fentanyl with fentanyl and midazolam in controlling pain in trauma patients

Protocol summary

Study aim
Comparison of the effect of fentanyl with fentanyl and midazolam in pain control in patients with limb trauma

Design
Parallel clinical trial with control group, triple blind , randomized using Random allocation software, on 78 limb traumatic patients

Settings and conduct
The study will be performed on limb trauma patients admitted to the emergency room of Imam Hossein Hospital in Shahroud. The intervention group will receive fentanyl and midazolam. The control group will receive fentanyl and placebo. Primary and secondary outcomes will be assessed in all patients before injection, 30 and 60 minutes after injection. Patients, outcome assessors (emergency medicine specialists), statistical analyzers using codes that do not know which ones to assign to the groups will be blinded in this study. In all patients, two identical intravenous injections will be performed without knowing the contents of the injected drug.

Participants/Inclusion and exclusion criteria
Conditions for study before randomization 1- People in the age group of 18 to 80 years 2. Mechanism of trauma Direct trauma 3. Obtaining conscious consent 4. The patient is fully conscious.(GCS=15) 5.Unstable hemodynamic status including patients with blood pressure less than 90 mm Hg Major conditions of non-inclusion before randomization 1. Pregnancy 2. Mentally retarded patient 3. Patients addicted to drugs 4. Consumption of psychotropic drugs

Intervention groups
In this study, interventions are divided into two groups: intervention and control. In the control group, fentanyl is injected intravenously and slowly as a placebo based on macro grams per kilogram and one milligram of normal saline. Fentanyl and midazolam are given slowly and intravenously to reduce pain.

Main outcome variables
Determining and comparing the level of pain and anxiety of patients in the two groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201226049832N1**
Registration date: **2021-04-19, 1400/01/30**
Registration timing: **prospective**

Last update: **2021-04-19, 1400/01/30**
Update count: **0**

Registration date
2021-04-19, 1400/01/30

Registrant information

Name
Mozhgan Sabzevari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3223 2986

Email address
sabzevari@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-25, 1400/02/05

Expected recruitment end date
2022-01-19, 1400/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of fentanyl with fentanyl and midazolam in controlling pain in trauma patients

Public title
Comparison of the effect of fentanyl with fentanyl and midazolam in pain control

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
People in the age group of 18 to 80 year Mechanism of trauma multiple trauma and direct trauma Obtaining informed consent Stable hemodynamic status (including patients with systolic blood pressure above 90 mm Hg) Patient consciousness is complete (GCS = 15)

Exclusion criteria:
Pregnancy.Mentally retarded patients Mentally retarded patients Consumption of psychotropic drugs Drug addicted patients

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into 2 groups of 39 using Random allocation software.From the first eligible patient, the criteria for inclusion of treatment allocation based on randomization will beginInitially, the number 1 to 78 will be written on 78 envelopes, respectively.Then, inside each envelope, a sheet containing the code of the type of treatment of each patient will be specified based on the Random allocation software, which will determine the treatment of each patient.The written consent form of the study will be placed .After the arrival of each patient or identification in accordance with the criteria for entering an envelope in the order of the numbers that the type of treatment will be assigned in code.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participant: The use of placebo in addition to the current drug in one group of fentanyl and normal saline injections and in the second group of fentanyl and midazolam injections. Outcome Evaluator: Measuring the patient's pain before and after the intervention by an emergency medicine resident who is unaware of how medications are administered to the patient.The data analyzer is not aware of how drugs are assigned to groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
research ethic committee Shahroud university of medial science

Street address
Shahroud University of Medical Sciences and Health Services, Hafte Tir Square

City
Shahroud

Province
Semnan

Postal code
۳۶۱۴۷۷۳۹۴۷

Approval date
2021-03-08, 1399/12/18

Ethics committee reference number
IR.SHMU.REC.1400.010

Health conditions studied

1

Description of health condition studied
Trauma

ICD-10 code
G89.11

ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
pain control in patient trauma

Timepoint
at the time of referral , 30 and 60 minutes after the intervention

Method of measurement
using the Visual Analogue Scale

Secondary outcomes

1

Description

Side effects of medications

Timepoint

30 and 60 minutes after the intervention

Method of measurement

Examination by a specialist

2

Description

Level of anxiety

Timepoint

At the time of referral, 60 minutes after referral

Method of measurement

Depression Anxiety Stress Scale

Intervention groups

1

Description

Fentanyl injection based on weight levels (Weight 40 to 50 kg at 45 micrograms. Weight 50 to 60 kg at 55 micrograms. Weight 60 to 70 micrograms at 65 micrograms. Weight 70 to 80 kg at 75 micrograms. Weight 80 to 90 kg at 85 micrograms. Weight 90 to 100 kg and above 100 micrograms) and inject one milligram of normal saline

Category

Treatment - Drugs

2

Description

Intervention group: Intravenous midazolam injection (1 mg under 50 kg. 2 mg 50 to 75 kg and 3 mg over 75 kg weight) and intravenous fentanyl injection based on weight levels (40 to 50 kg at 45 µg. 50 to 60 kg at 55 µg) Weight 60 to 70 micrograms at a rate of 65 micrograms. Weight 70 to 80 kg at a rate of 75 micrograms. Weight 80 to 90 kg at a rate of 85 micrograms. Weight 90 to 100 kg and above 100 micrograms)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department Emam Hossein hospital

Full name of responsible person

Mozhgan Sabzevari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

mozhgan sabzevari

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected data will be shared after identifying individuals and analyzing them.
When the data will become available and for how long
The end of the year 1401
To whom data/document is available
For all researchers
Under which criteria data/document could be used
For use in studies
From where data/document is obtainable
Supervisor
What processes are involved for a request to access data/document
Justification for use via email correspondence
Comments