Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Fentanyl versus Methadone in the Treatment of Withdrawal Syndrome of Addicted Patients Admitted to Toxicology ICU

Protocol summary

Study aim
To compare methadone and fentanyl in treatment of opioid withdrawal syndrome in addicted patients admitted to toxicology ICU

Design
Prospective, single-blinded, controlled pilot

Settings and conduct
In a prospective, single-blinded, controlled pilot, opioid-dependent intubated patients admitted to toxicology ICU of Loghman Hakim Hospital will alternately be assigned into either fentanyl or methadone groups. In the methadone group, they will be put on subcutaneous methadone with the initial dose of 10 mg every 12 hours (20 mg/day) as the initiation dose. The dose was subsequently adjusted based on the patients' signs and symptoms. In the fentanyl group, the patients will be put on intravenous administration of fentanyl with the initial dose of 50-100 µg/hour and adjusted subsequently based on the patients' response. the two groups will then be compared regarding response to treatment (COWS Scale) and time needed to respond to therapy and obviation of the withdrawal syndrome.

Participants/Inclusion and exclusion criteria
Addicted patients who are intubated and admitted to toxicology ICU are those with potential inclusion criteria. If their signs and symptoms of withdrawal initiate during ICU stay (with any severity of withdrawal) they will be included. Addiction will be confirmed by the history taken from the patients' next of kin, positive urine tests, and initiation of clinical opiate withdrawal syndrome determined by clinical opiate withdrawal scale (COWS) Patients with any other dependencies (such as dependency to benzodiazepines, SSRIs, etc) will be excluded Patients who receive any medication for control of the addiction before initiation of the withdrawal signs and symptoms, will also be excluded.

Intervention groups
Group 1: Patients receiving Fentanyl Group 2: Patients receiving Methadone

Main outcome variables
esponse to treatment and time needed to respond to therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150110020624N2**
Registration date: **2021-09-11, 1400/06/20**
Registration timing: **retrospective**

Last update: **2021-09-11, 1400/06/20**
Update count: **0**

Registration date
2021-09-11, 1400/06/20

Registrant information

Name
Nasim Zamani

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-20, 1399/08/30

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
2020-08-21, 1399/05/31

Actual recruitment end date
2021-05-21, 1400/02/31
Trial completion date
2021-08-10, 1400/05/19

Scientific title
Fentanyl versus Methadone in the Treatment of Withdrawal Syndrome of Addicted Patients Admitted to Toxicology ICU

Public title
Fentanyl versus Methadone and treatment of Withdrawal Syndrome In addicted patients admitted to toxicology ICU
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Addicted patients who are intubated and admitted to toxicology ICU are those with potential inclusion criteria. If their signs and symptoms of withdrawal initiate during ICU stay (with any severity of withdrawal) they will be included. Addiction will be confirmed by the history taken from the patients' next of kin, positive urine tests, and initiation of clinical opiate withdrawal syndrome determined by clinical opiate withdrawal scale (COWS).
Exclusion criteria:
Patients with any other dependencies (such as dependency to benzodiazepines, SSRIs, etc) will be excluded. Patients who receive any medication for control of the addiction before initiation of the withdrawal signs and symptoms, will also be excluded.
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the patients will be blinded to the type of treatment they are being given as they are unconscious and intubated.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Yaman Street- Velenjak
City
Tehran
Province
Tehran
Postal code
1971653313
Approval date
2020-08-09, 1399/05/19
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.457

Health conditions studied

1

Description of health condition studied
Withdrawal syndrome
ICD-10 code
F11.23
ICD-10 code description
ICD-10 F11.23 is a billable code used to specify a medical diagnosis of opioid dependence with withdrawal.

Primary outcomes

1

Description
Time to alleviation of withdrawal syndrome and the potency of treatment performed based on COWS scale
Timepoint
0.5 and 2 hours post administration
Method of measurement
COWS Scale (Clinical Opiate Withdrawal Scale)

Secondary outcomes

1

Description
Time to extubation- Development of complications
Timepoint
1 and 2 weeks after ICU admission
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: The patients are put on fentanyl with

the initial dose of 50-100 microg/h. This dose will eventually be adjusted based on the patient response and alleviation of the signs and symptoms of withdrawal.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Loghman Hakim Toxicology ICU

Full name of responsible person
NASIM ZAMANI

Street address
Makhsus- South Karegar Street

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Sponsors / Funding sources

1

Sponsor

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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
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
50

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nasim Zamani

Position
Attending Physician

Latest degree
Subspecialist

Other areas of specialty/work
Toxicology

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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
The patients' data and analysis data are available and can be used after anonymization of them.
When the data will become available and for how long
After publication of the data
To whom data/document is available
Anyone needing the data for scientific and academic purposes
Under which criteria data/document could be used
The data can be used for any scientific purpose with mentioning the source of the data
From where data/document is obtainable
Nasim Zamani
What processes are involved for a request to access data/document
None- Emailing the abovementioned person
Comments