Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Efficacy and safety of Fentanyl Sublingual for treatment of Breakthrough Pain in Patients with Cancer

Protocol summary

Study aim
Investigating the effect and safety of sublingual fentanyl in the treatment of break through pain in cancer patients

Design
Clinical trial with intervention and placebo groups,100 patients sample size, Trial phase 2-3.Simple randomization based on random numbers table, in this method, we set a set of numbers without a specific pattern and order,and completely randomly in the table,we will read the table numbers from the direction above.For the intervention group,we consider the even numbers and the placebo group for the odd numbers,Then put on one of the numbers and move upwards,register the number and assign one to an intervention or placebo group.

Settings and conduct
Tertiary regional and teaching hospital.Participants including criteria,among the patients who were candidates for Intake of fentanyl sublingual referred to the Akhtar Hospital in 2019,100 were selected by Sequential method,and accidentally divided into two groups of placebo and intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age 18 and above Patients with soft,visceral and bone marrow malignancies,At least1-4 episodes of pain per day,Receiving an opioid regimen for the control of pain.Exclusion criteria:History of receiving interatcal opioids,Having a condition that affects subcutaneous fentanyl tolerance or absorption of buccal mucosa,Any sudden increase in unrelated cancer pain.

Intervention groups
Intervention group:Fentanyl Sublingual tablet: In our study, the available doses of 100 and 200 µg subcutaneous fentanyl.Patients start fentanyl Sublingual 200 /100 micrograms after initiating a sudden pain attack.Placebo group: Placebo tablets are similar to fentanyl sublingual 100 and 200 micrograms. The patient uses a sublingual fentanyl and an oral opioid diet of between 1000 and 60 mg per day/oral oxycodone 30 mg daily for pain relief.

Main outcome variables
Pain intensity;Episode of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131124015515N8**
Registration date: **2019-08-02, 1398/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-02, 1398/05/11**
Update count: **0**

Registration date
2019-08-02, 1398/05/11

Registrant information

Name
Masoud Hashemi

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 2261 2252

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dr.hashemi@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-22, 1398/04/31

Expected recruitment end date
2019-09-10, 1398/06/19

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy and safety of Fentanyl Sublingual for treatment of Breakthrough Pain in Patients with Cancer

Public title
The effect of sublingual fentanyl pill in the treatment of sudden pain in patients with cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 and above Patients with soft, visceral and bone marrow malignancies, patients with a diagnosis of malignant tumors or malignant tumors At least 1-4 episodes of pain per day Receiving an opioid regimen for the control of pain at a constant and similar dose (oral morphine or opioid similar to 60-1000 mg / day / oral oxycodone 30 mg daily) Having informed consent to participate in the study
Exclusion criteria:
History of receiving interatcal opioids Patients with history of mucositis / osteomathitis Grade II and above based on the definition of the terminology of the incidence of complications Having a condition that affects subcutaneous fentanyl tolerance or absorption of buccal mucosa Pregnancy / Breastfeeding Sleep apnea Active metastasis in the brain by increasing intracranial pressure Chronic lung obstruction Renal or liver dysfunction Brady's remarkable arrhythmias have not been diagnosed with heart disease Any sudden increase in unrelated cancer pain Conscious unwillingness to participate in the study
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization based on random numbers table
Blinding (investigator's opinion)
Double blinded
Blinding description
Participant and clinical outcomes evaluator are not aware of the code assigned to each of the groups.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Cancer Research Center of Shahid Beheshti University of Medical Sciences
Street address
Tajrish square, Shohada Tajrish Hospital
City
Tehran
Province
Tehran
Postal code
1989934148
Approval date
2019-06-29, 1398/04/08
Ethics committee reference number
IR.SBMU.CRC.REC.1398.001

Health conditions studied

1

Description of health condition studied
Breakthrough Pain in Patients with Cancer
ICD-10 code
G89.3
ICD-10 code description
Neoplasm related pain (acute) (chronic)

Primary outcomes

1

Description
Pain intensity
Timepoint
At the onset of the episode before the start of the drug, 15, 30, 45 and 60 minutes after starting treatment
Method of measurement
The severity of pain is measured using a numeric rating scale (NRS-11) (0 = painless, mild 1-3, moderate 6-4, severe 10-7).

2

Description
Episode of pain
Timepoint
Every time a breakthrogh pain occurs.
Method of measurement
Recorded by patients

Secondary outcomes

1

Description
Side effects
Timepoint
After taking each dose of medicine
Method of measurement
Recorded by patient

Intervention groups

1

Description
Intervention group: Fentanyl Sublingual tablet: In our study, the available doses of 100 and 200 µg subcutaneous fentanyl: Faran Chemical Co., Iran. Patients are required to record the baseline pain score after the start of a sudden pain attack, then start fentanyl sublingual 100 micrograms. Patients can use other opioids that are used in the study, if they do not improve the patient's pain satisfactorily within 30 minutes after the initial dosage is dissolved. Usually, breakthrough pain onset of subsequent pain occurs at least 4 hours after receiving fentanyl sublingual or other opioids used in the study. If a dose of 100 µg did not improve the patient's satisfactory pain and the side effects of the medication could be tolerated, a sudden attack of the next pain could be done using 200 µg fentanyl Sublingual .
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet: Similar to fentanyl Sublingual of 100 and 200 micrograms: Faran Chemical Company-Country: Iran. The control group used sublingual fentanyl from placebo and the oral opioid diet of 60-1000 mg / day / oral ocicidone 30 mg daily for relief of pain.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar Hospital
Full name of responsible person
Masoud Hashemi MD
Street address
Pain Clinic, Akhtar Hospital, Sharifi Manesh st.
City
Tehran
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1964714953
Phone
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Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi MD.
Street address
Shahid Arabi st., Yaman St., Shahid Chamran Expressway
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1985717443
Phone
+98 21 2243 9781
Email
zarghi@sbmu.ac.ir
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
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masoud Hashemi MD.
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work

Anesthesiology
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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 whole data can be shared after unidentifiable people.
When the data will become available and for how long
En Start the access period 12 months after printing the results
To whom data/document is available
Only available to scholars working in academic and academic institutions
Under which criteria data/document could be used
Employed in research centers
From where data/document is obtainable
Person responsible for scientific inquiries
What processes are involved for a request to access data/document
Send email to person responsible for scientific inquiries
Comments