

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 least 1-4 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)

Phone

+98 21 2261 2252

Email address

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

AgeFrom **18 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget 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 breakthrough 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 oxycodone 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.

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Tehran

Postal code

1964714953

Phone

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Fax

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Email

dr.hashemi@sbmu.ac.ir

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

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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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Akhtar Hospital, Sharifi Manesh st.

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

Contact

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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